



US010322271B2

(12) **United States Patent**
Levy et al.

(10) **Patent No.:** **US 10,322,271 B2**
(45) **Date of Patent:** **Jun. 18, 2019**

(54) **DELIVERY SYSTEM AND METHOD FOR THE EFFECTIVE AND RELIABLE DELIVERY OF CONTROLLED AMOUNTS OF A MEDICAL FLUID**

(71) Applicants: **Frank Levy**, Fort Myers, FL (US);
Kimberley Levy, Fort Myers, FL (US)

(72) Inventors: **Frank Levy**, Fort Myers, FL (US);
Kimberley Levy, Fort Myers, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/696,730**

(22) Filed: **Sep. 6, 2017**

(65) **Prior Publication Data**
US 2018/0236214 A1 Aug. 23, 2018

Related U.S. Application Data
(63) Continuation-in-part of application No. 15/053,530, filed on Feb. 25, 2016, now Pat. No. 10,155,093, (Continued)

(51) **Int. Cl.**
A61M 5/00 (2006.01)
A61K 9/12 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC *A61M 35/003* (2013.01); *A01N 25/00* (2013.01); *A61M 5/00* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 35/00; A61M 25/0028; A61M 25/003; A61M 25/0071; A61M 3/005;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,475,511 A 7/1949 Nicholson
2,631,321 A 3/1953 Mureau
(Continued)

FOREIGN PATENT DOCUMENTS

CN 2179152 Y 10/1994
DE 10161027 A1 6/2003
(Continued)

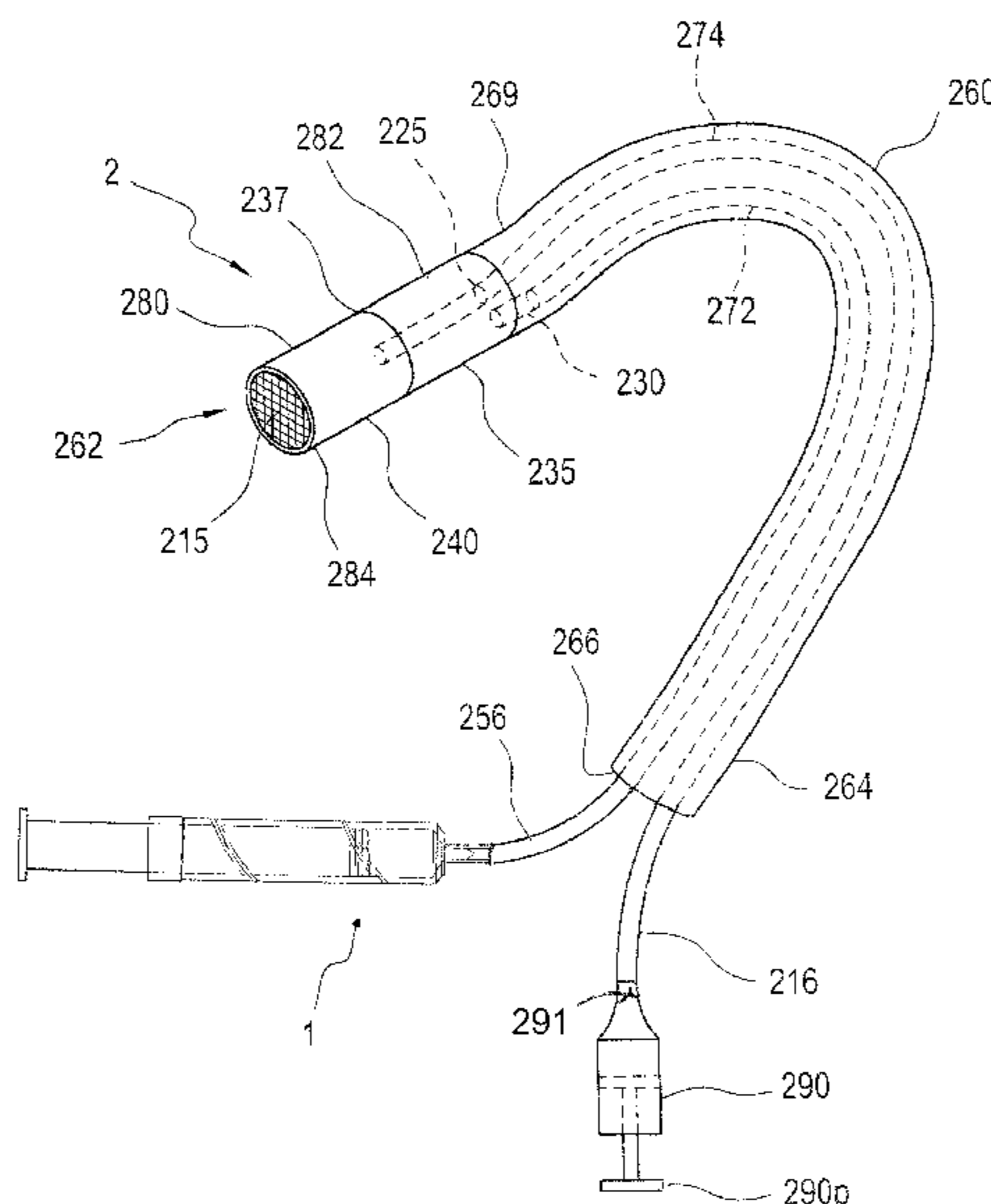
Primary Examiner — Edelmira Bosques

(74) *Attorney, Agent, or Firm* — Welsh Flaxman & Gitler LLC

(57) **ABSTRACT**

A medical fluid suspension generating apparatus for performing medical procedures includes a Venturi-agitating tip assembly composed of a multi-channel arrangement at a proximal first end thereof and a tip at a distal second end thereof. The apparatus also includes a compressed medical fluid unit fluidly connected to the multi-channel arrangement at a proximal first end of the Venturi-agitating tip assembly and a medical solution fluidly connected to the multi-channel arrangement at a proximal first end of the Venturi-agitating tip assembly. Pressurized sclerosant or other chemical medical solution, from the compressed medical fluid unit, and the medical solution of sclerosant or other chemical medical solution are combined within the Venturi-agitating tip assembly in a manner generating an enriched medical suspension that is ultimately dispensed from the suspension delivery apparatus to spray or wash the inner wall of a lumen.

14 Claims, 10 Drawing Sheets



Related U.S. Application Data

which is a continuation-in-part of application No. 14/509,459, filed on Oct. 8, 2014, now Pat. No. 9,744,342, which is a continuation of application No. 13/068,680, filed on May 17, 2011, now Pat. No. 8,876,749, which is a continuation-in-part of application No. 12/652,845, filed on Jan. 6, 2010, now abandoned, which is a continuation-in-part of application No. 12/210,368, filed on Sep. 15, 2008, now abandoned, which is a continuation-in-part of application No. 11/945,674, filed on Nov. 27, 2007, now Pat. No. 7,543,760.

(60) Provisional application No. 62/121,827, filed on Feb. 27, 2015, provisional application No. 60/867,323, filed on Nov. 27, 2006.

(51) **Int. Cl.**

A61M 25/00 (2006.01)
A61M 35/00 (2006.01)
A61M 37/00 (2006.01)
A01N 25/00 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**

CPC *A61M 25/0071* (2013.01); *A61M 35/00* (2013.01); *A61M 37/00* (2013.01); *A61B 2017/00884* (2013.01); *A61B 2017/00893* (2013.01); *A61K 9/124* (2013.01); *A61M 2025/0036* (2013.01); *A61M 2025/0073* (2013.01)

(58) **Field of Classification Search**

CPC .. *A61M 5/2066*; *A61M 5/3294*; *A61M 16/12*; *A61M 16/127*; *A01N 25/00*
 See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,688,428 A 9/1954 Manhartsberger
 2,789,304 A 4/1957 Leavin
 2,828,889 A 4/1958 Joschko
 3,004,686 A 10/1961 McKee
 3,034,332 A 5/1962 Lederer
 3,268,939 A 8/1966 Aversa
 3,426,768 A 2/1969 Vardaros
 3,831,844 A 8/1974 Tropeano et al.
 3,879,703 A 4/1975 Bonazoli et al.
 4,135,269 A 1/1979 Marston
 4,189,068 A 2/1980 Apellaniz
 4,219,021 A 8/1980 Fink
 4,567,905 A 2/1986 Stewart et al.
 4,596,261 A 6/1986 Renda et al.
 4,744,356 A 5/1988 Greenwood
 4,786,394 A 11/1988 Enzer et al.
 4,950,230 A 8/1990 Kendell
 5,109,877 A 5/1992 Takeda
 5,135,026 A 8/1992 Manska
 5,154,348 A 10/1992 Ratnik et al.
 5,195,963 A 3/1993 Yafuso et al.

5,246,140 A 9/1993 Thix et al.
 5,345,932 A 9/1994 Yafuso et al.
 5,395,318 A 3/1995 Kaprelian
 5,580,530 A 12/1996 Kowatsch et al.
 5,699,961 A 12/1997 Ratnik et al.
 5,815,877 A 10/1998 Haneveld
 D401,419 S 11/1998 Hartmann et al.
 5,926,903 A 7/1999 Kim
 6,070,594 A 6/2000 Mears
 6,070,597 A 6/2000 Motherhead
 6,164,556 A 12/2000 Dupre et al.
 6,192,883 B1 2/2001 Miller, Jr.
 6,295,007 B1 9/2001 O'Meara
 6,315,762 B1 11/2001 Recinella et al.
 6,378,570 B1 4/2002 Shipachev et al.
 6,402,047 B1 6/2002 Thomas
 6,461,568 B1 10/2002 Eckhardt
 6,474,091 B2 11/2002 Guerra
 6,572,873 B1 6/2003 Osman et al.
 6,895,624 B2 5/2005 Fischer et al.
 6,997,321 B2 2/2006 Young
 7,162,802 B2 1/2007 Barnardeau et al.
 7,543,760 B2 6/2009 Levy et al.
 7,918,620 B2 4/2011 Del Ponte
 8,074,666 B2 12/2011 Piao
 8,132,285 B2 3/2012 Piao
 9,011,031 B2 4/2015 Piao
 2001/0044618 A1 11/2001 Recinella et al.
 2002/0017328 A1 2/2002 Loo
 2002/0174578 A1 11/2002 Ross
 2003/0034459 A1 2/2003 Bonin
 2003/0181850 A1 9/2003 Diamond et al.
 2004/0168700 A1 9/2004 Dorf
 2005/0000981 A1 1/2005 Peng et al.
 2005/0092315 A1 5/2005 Bachelder
 2005/0103342 A1 5/2005 Jorczak et al.
 2005/0119607 A1 6/2005 Van Der Linden et al.
 2006/0004322 A1 1/2006 Uesugi et al.
 2006/0071091 A1 4/2006 Ratnik
 2006/0074386 A1 4/2006 Wollmann
 2006/0175554 A1 8/2006 Riddell
 2006/0178620 A1 8/2006 Wollmann
 2007/0104616 A1 5/2007 Keenan et al.
 2007/0111298 A1 5/2007 Muller et al.
 2008/0004549 A1 1/2008 Anderson et al.
 2008/0120992 A1 5/2008 Levy et al.
 2008/0167621 A1 7/2008 Wagner et al.
 2009/0062741 A1 3/2009 Smith et al.
 2009/0318890 A1 12/2009 Levy
 2010/0101579 A1 4/2010 Levy
 2010/0152880 A1* 6/2010 Boyden A61K 9/0019
 700/117
 2011/0112041 A1 5/2011 Schiffmann
 2011/0218411 A1 9/2011 Keenan et al.
 2012/0305669 A1* 12/2012 Meron A61B 17/00491
 239/428
 2017/0153165 A1* 6/2017 Nwadigo B01L 3/0217

FOREIGN PATENT DOCUMENTS

EP 2468204 A1 6/2012
 WO WO00/72821 12/2000
 WO WO02/41872 5/2002
 WO WO2005/048984 6/2005

* cited by examiner

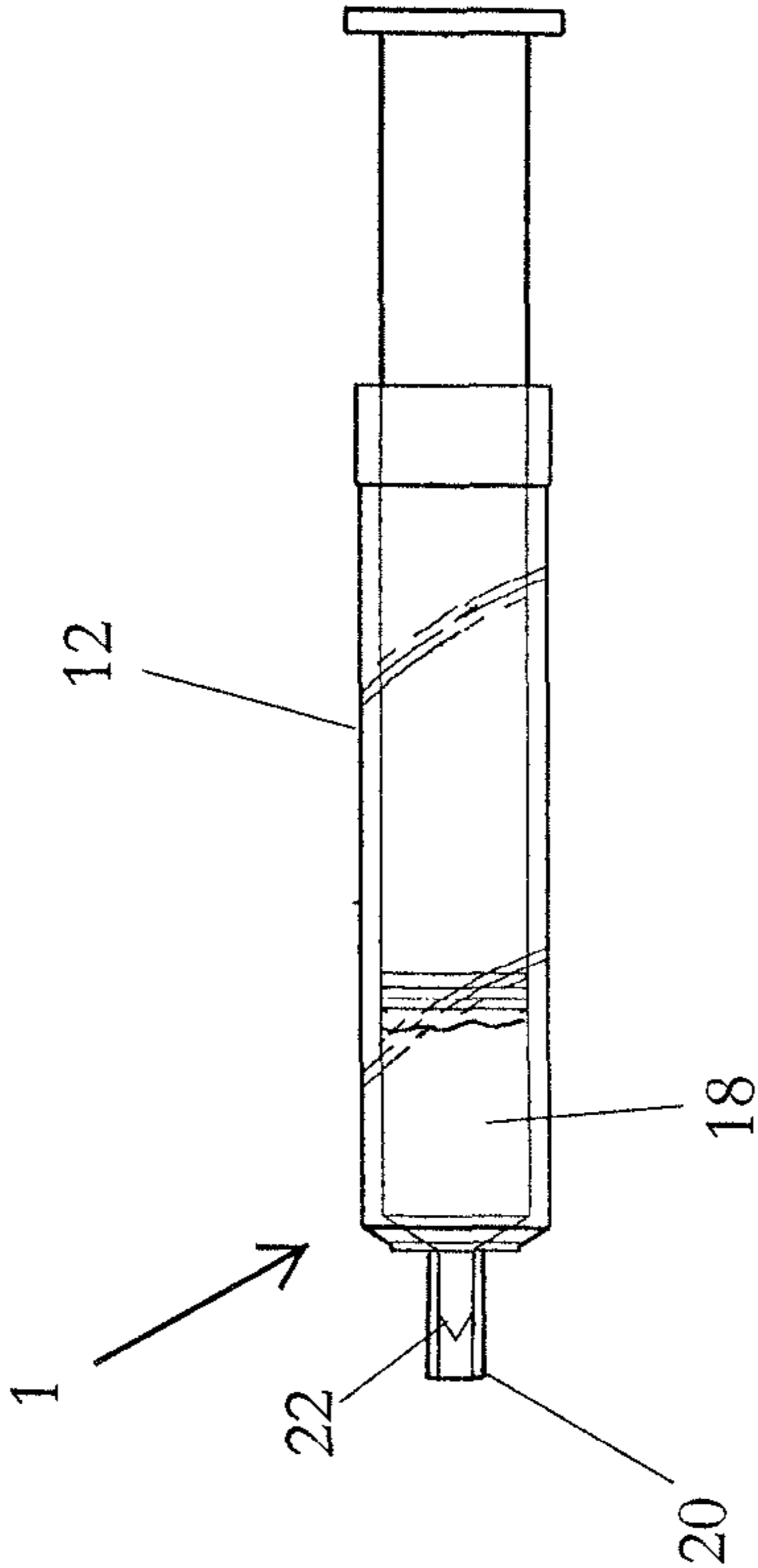
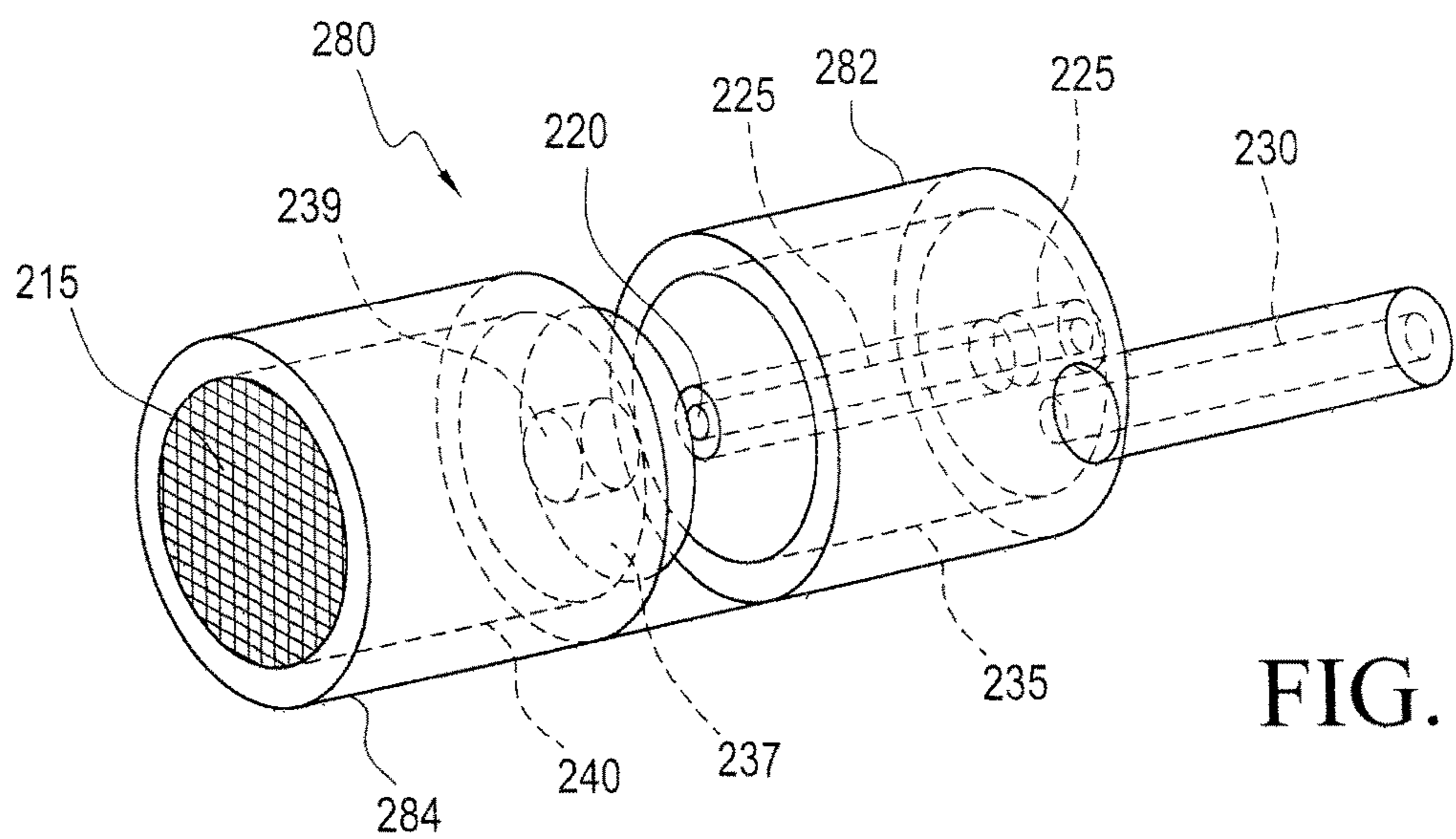
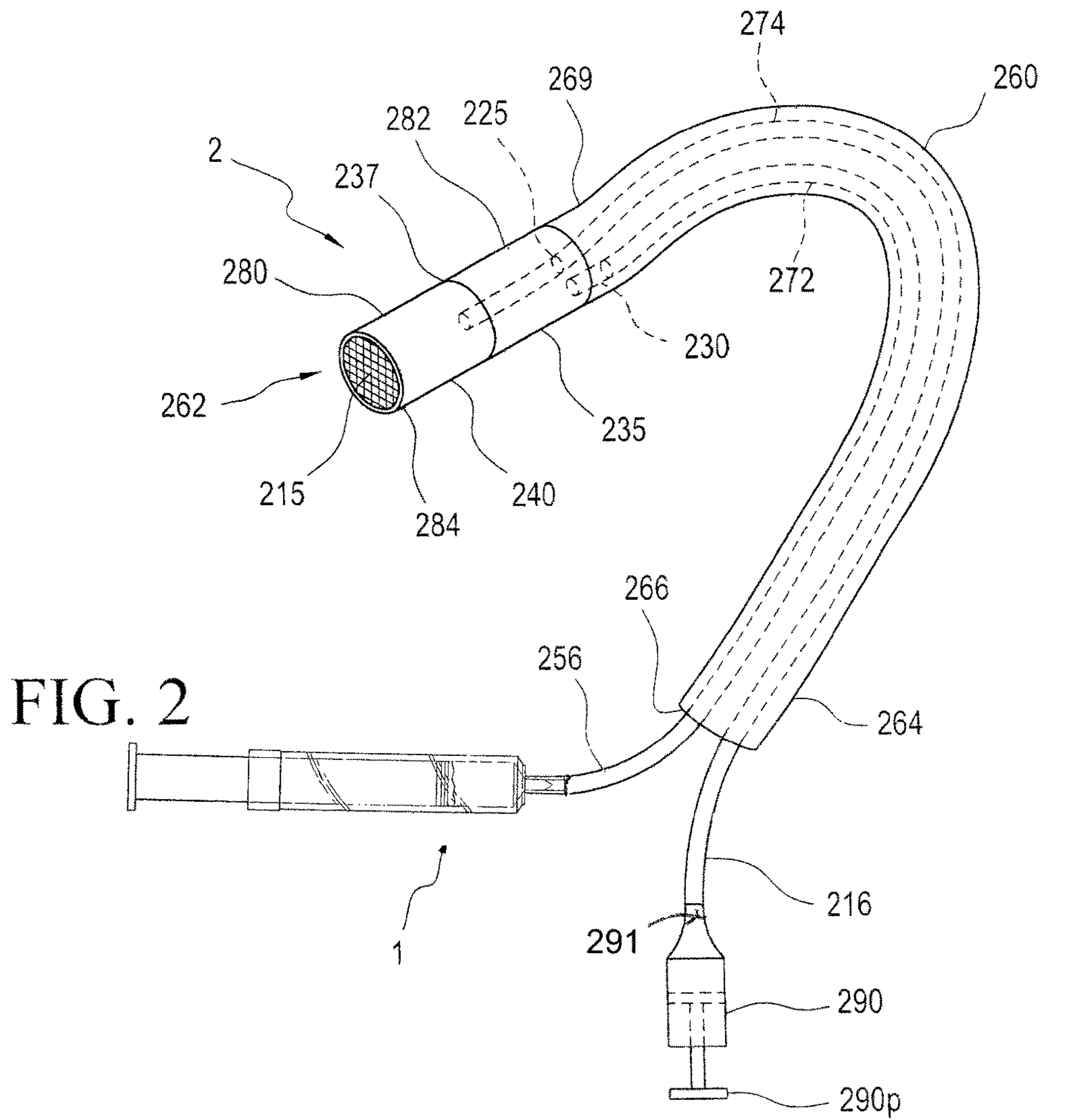


FIG. 1



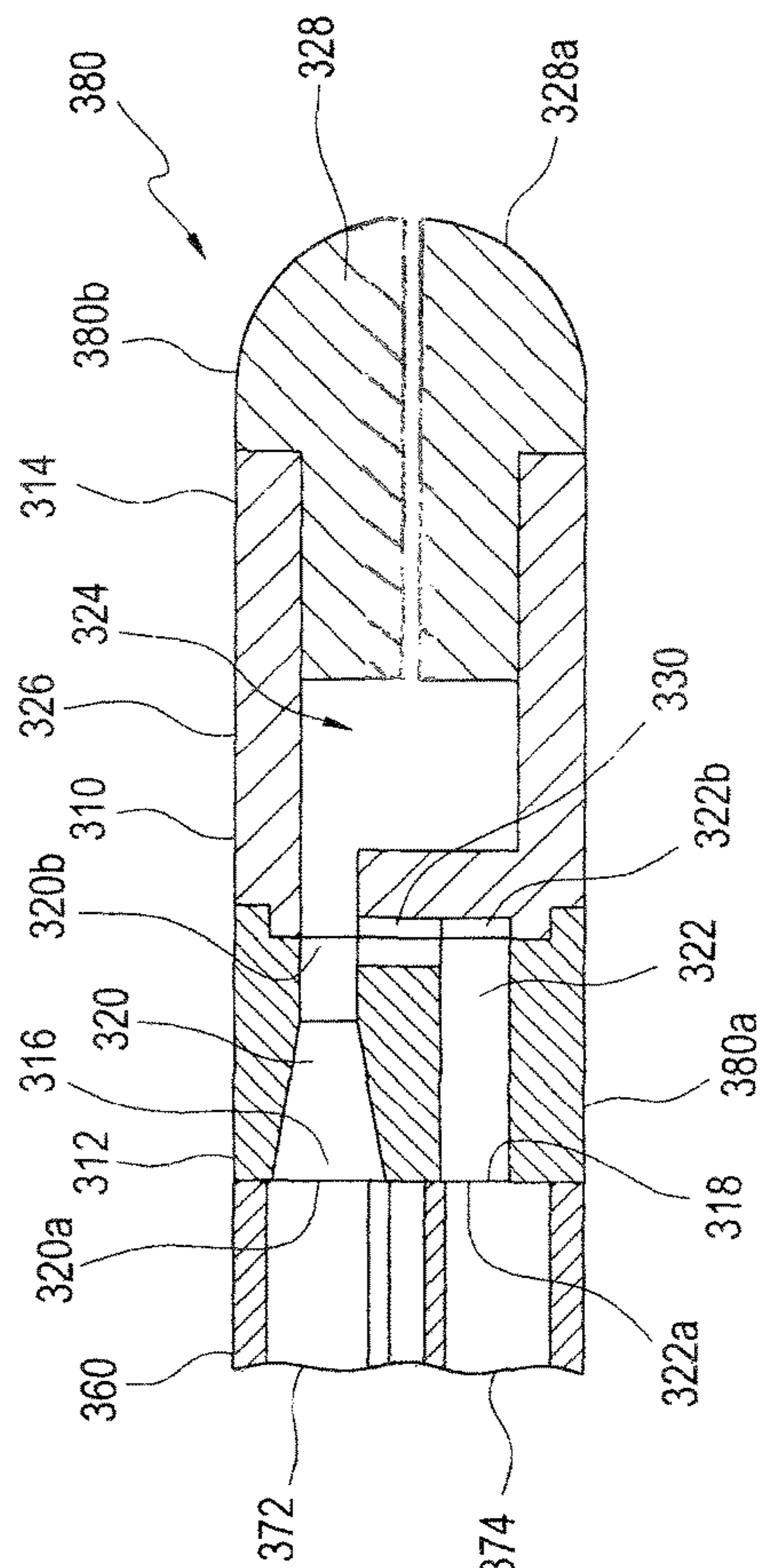


FIG. 4A

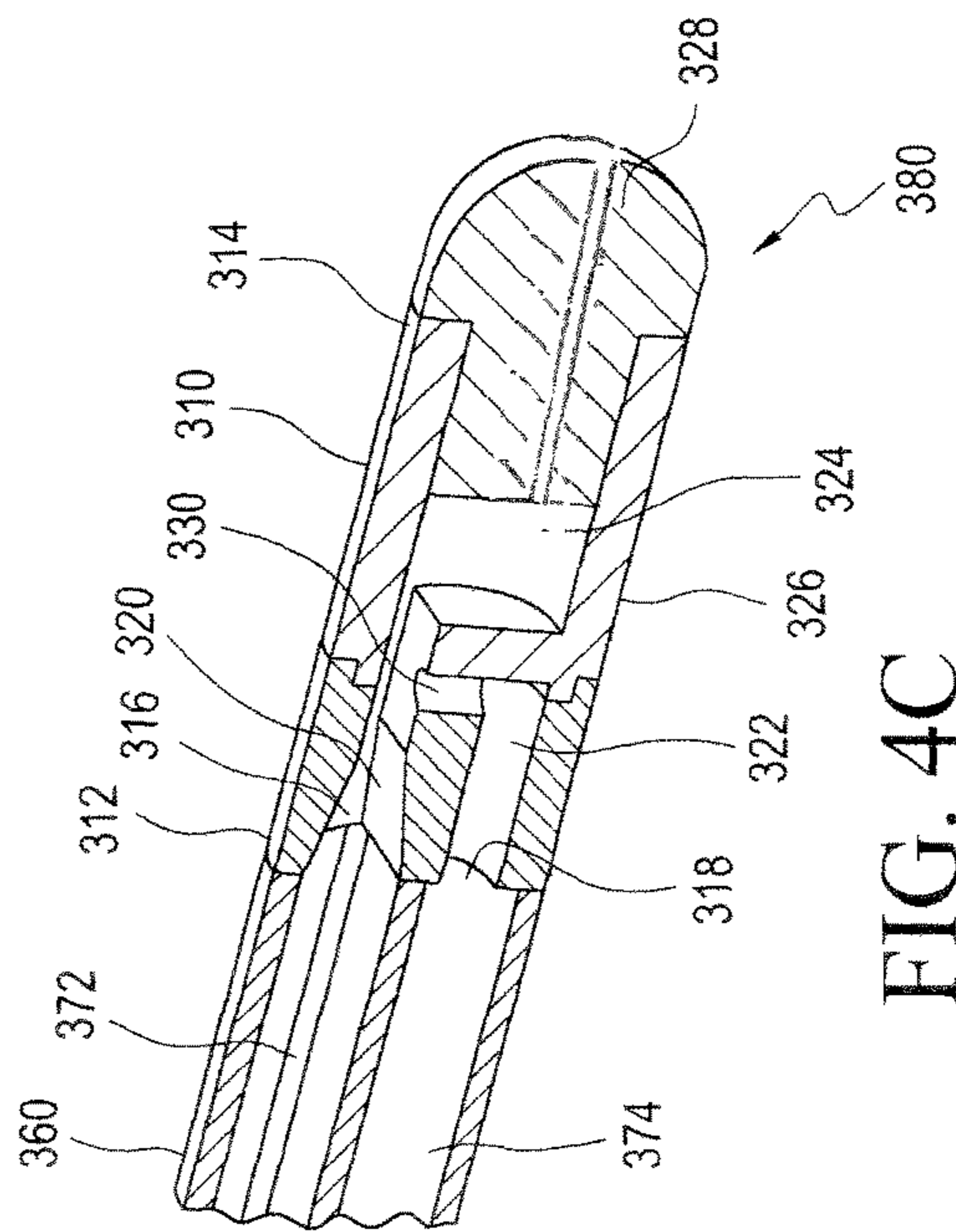


FIG. 4C

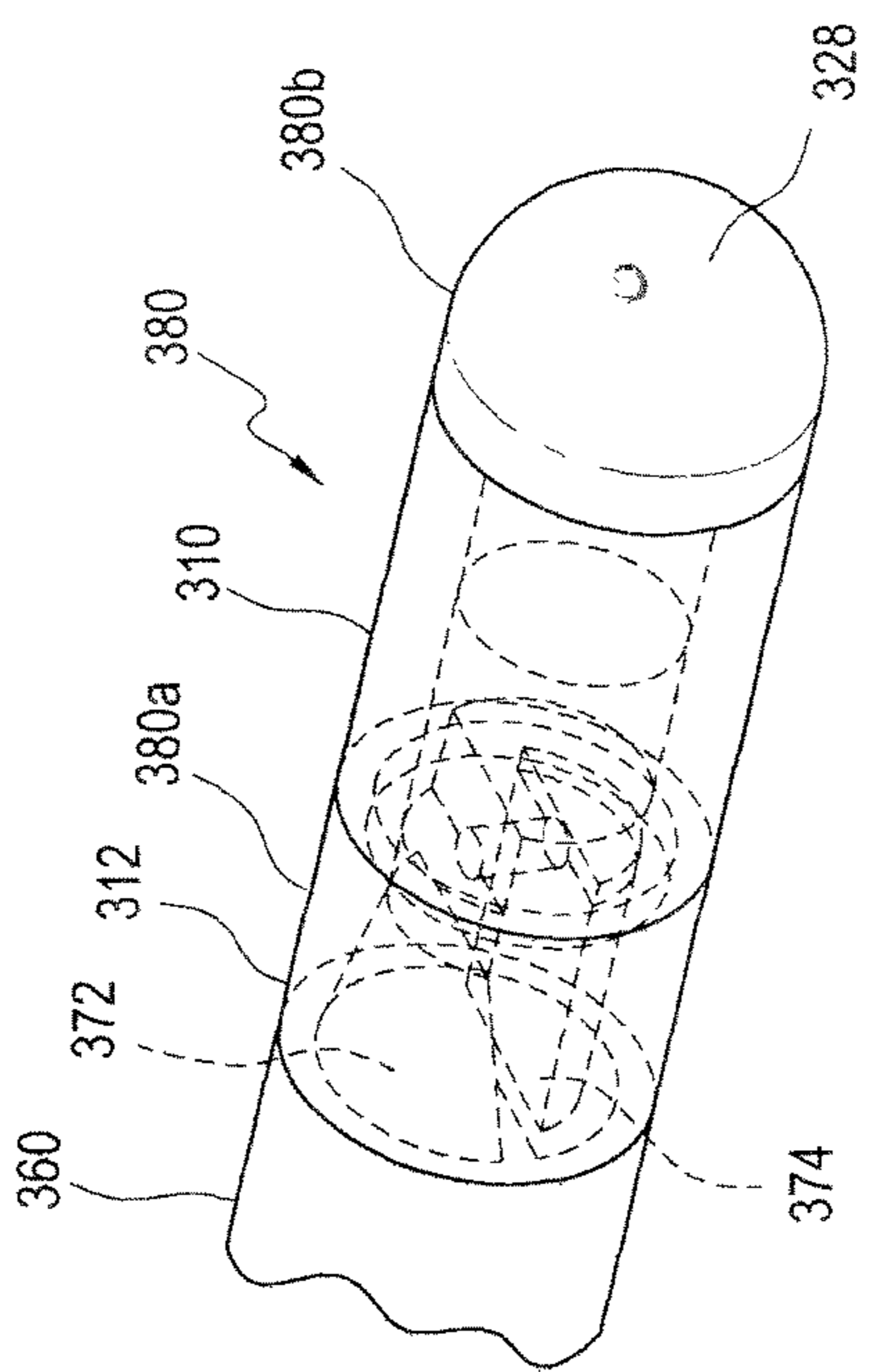


FIG. 4B

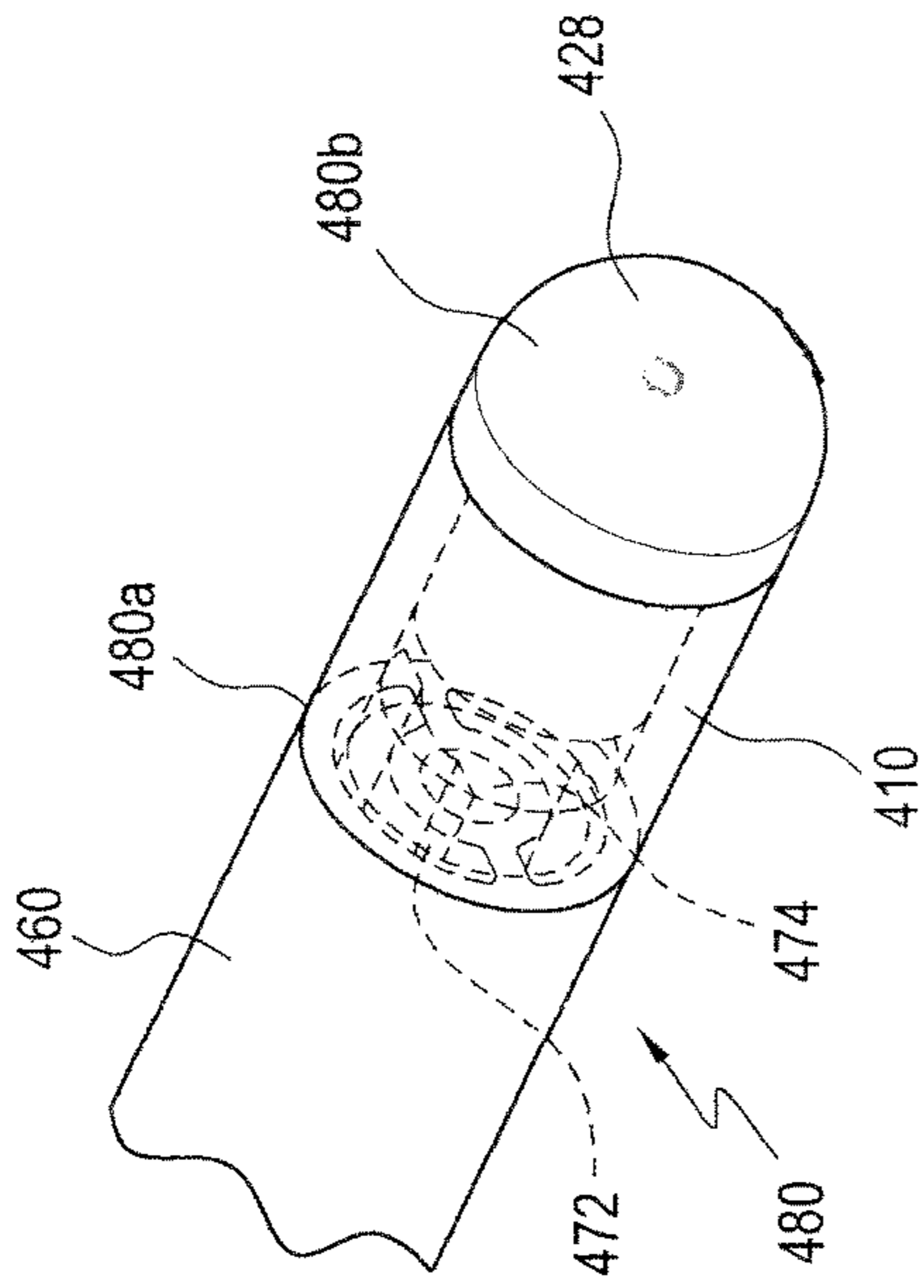


FIG. 5A

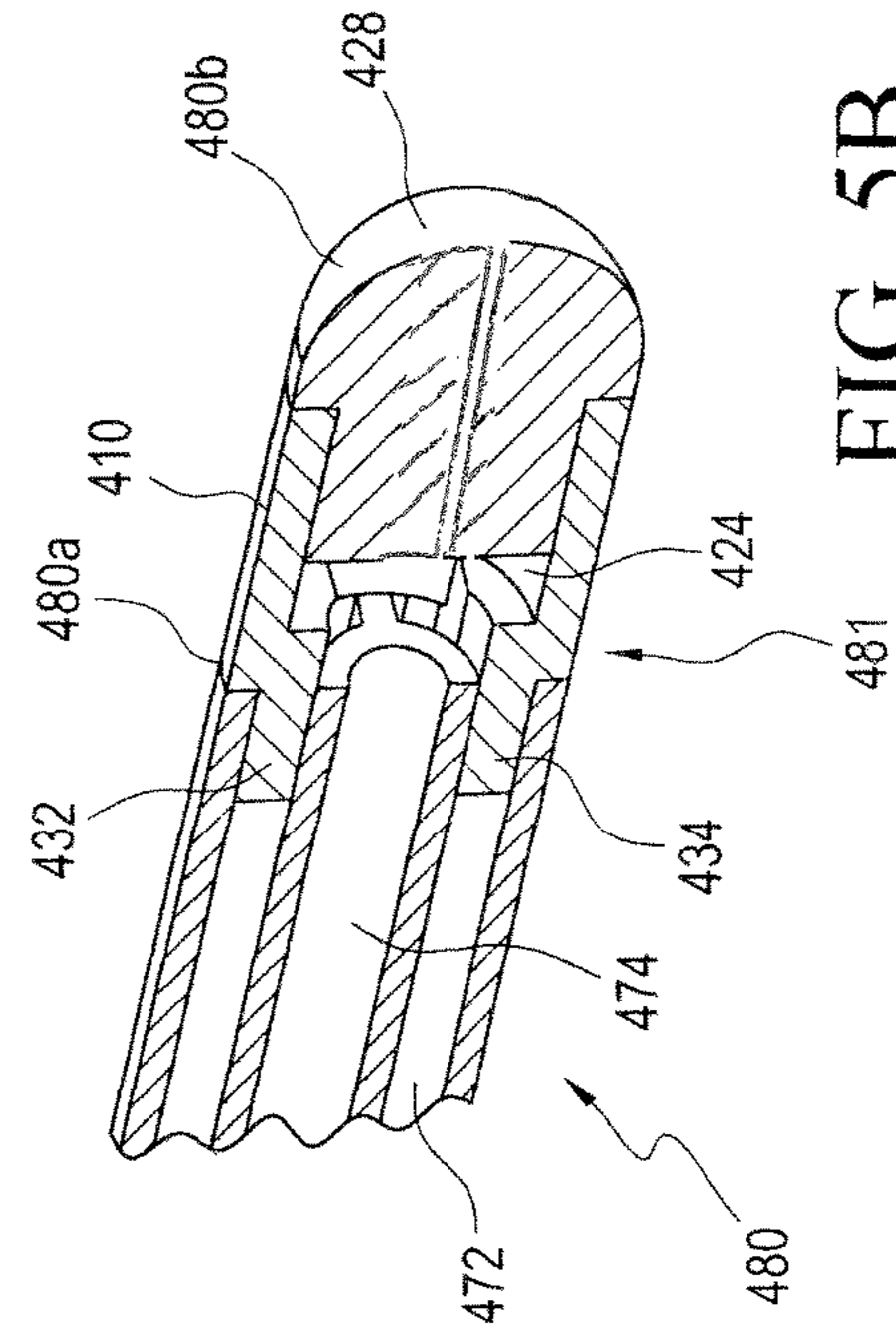


FIG. 5B

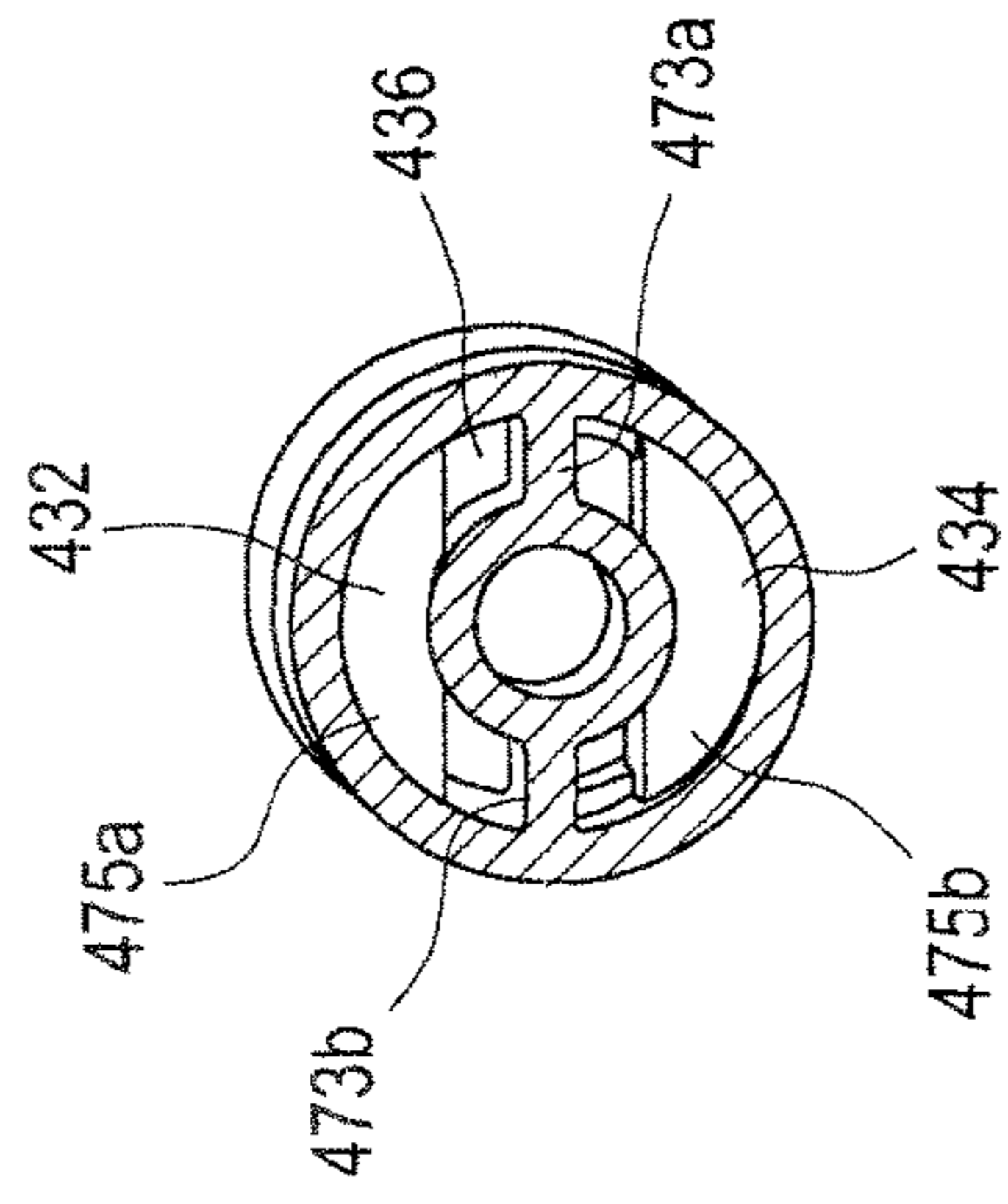


FIG. 5D

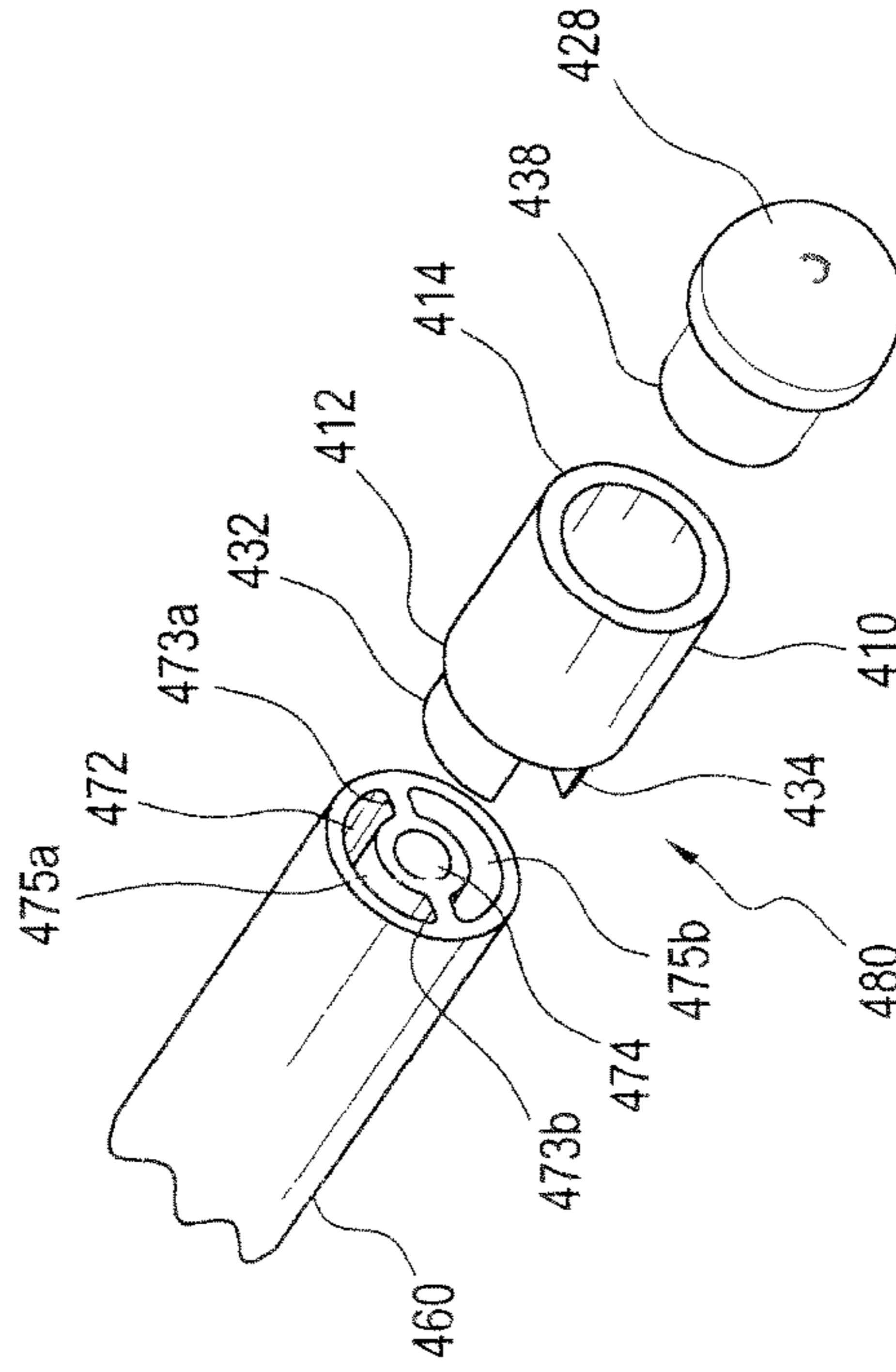


FIG. 5C

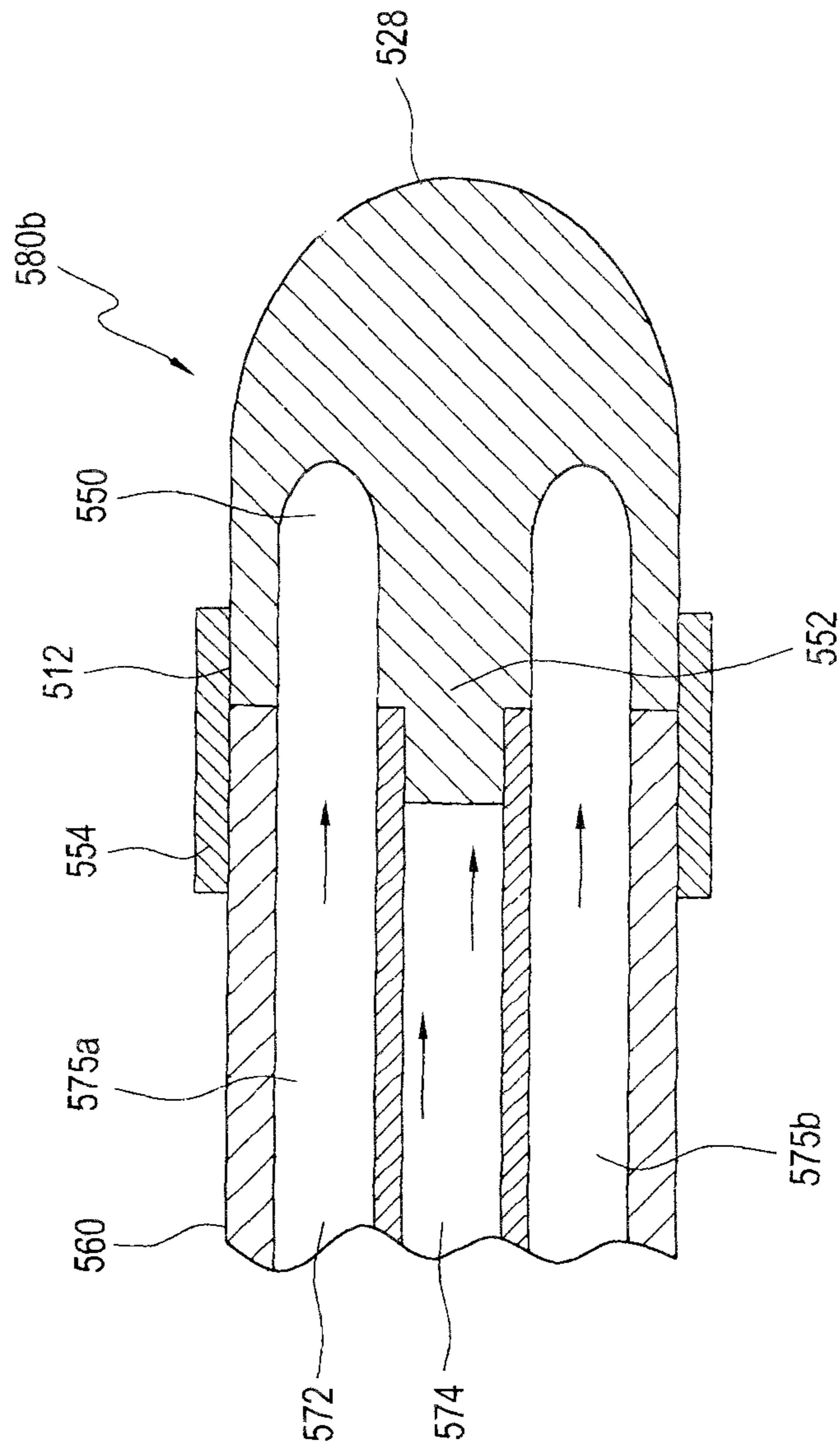


FIG. 6

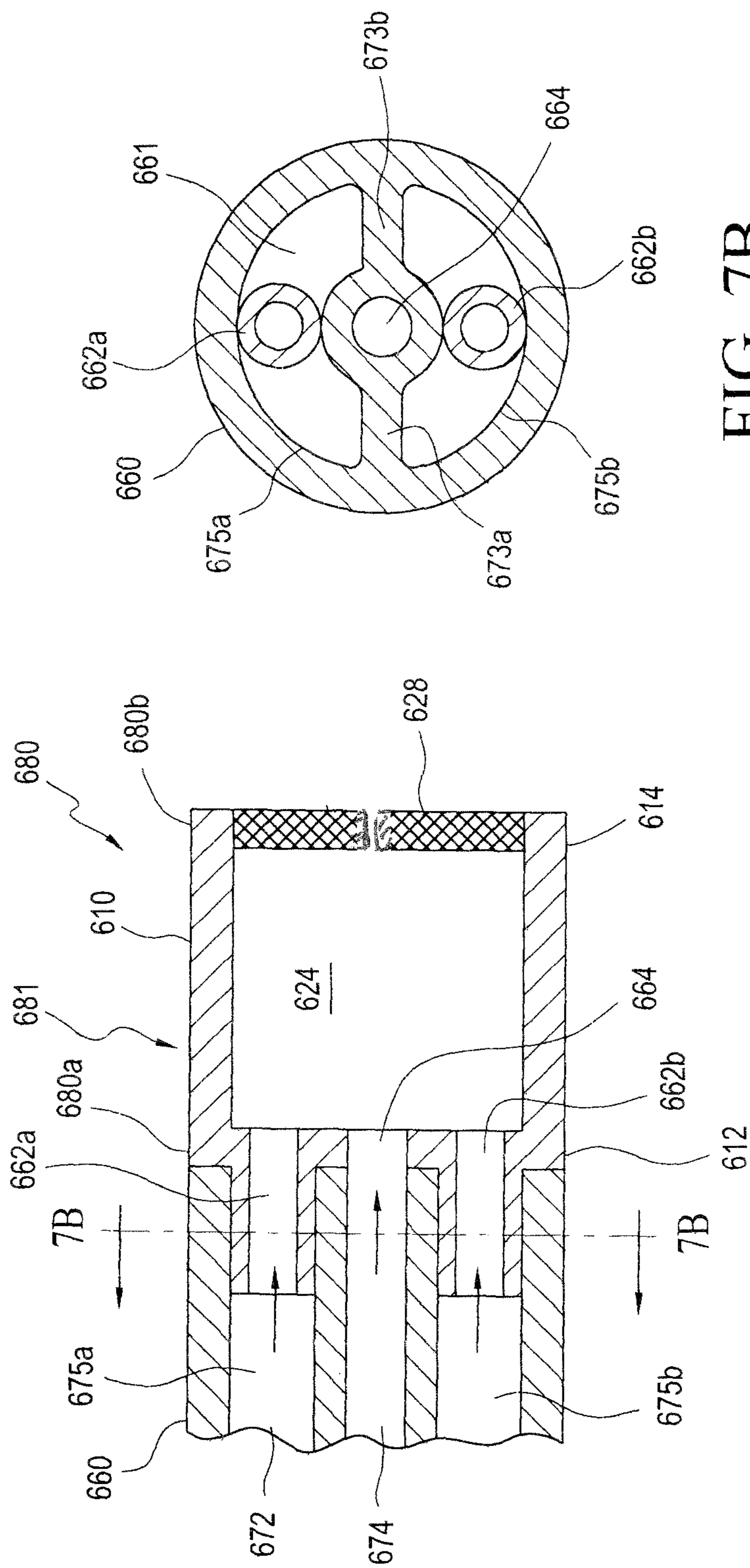
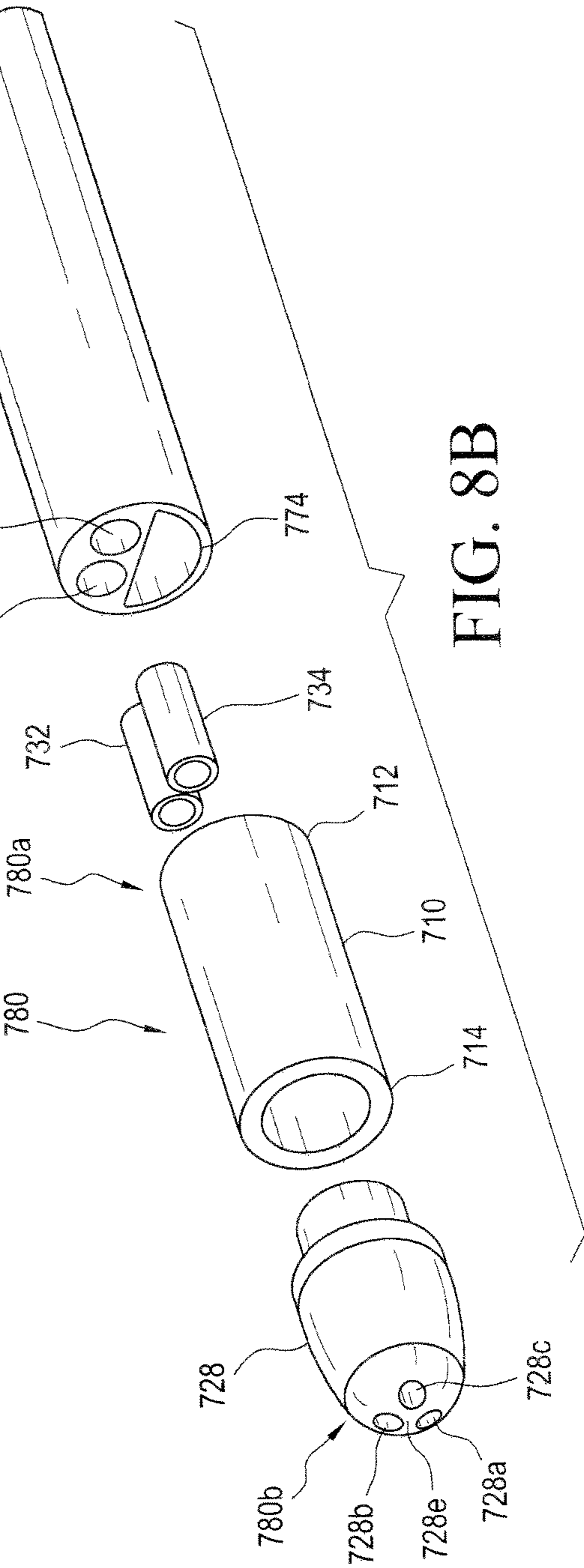
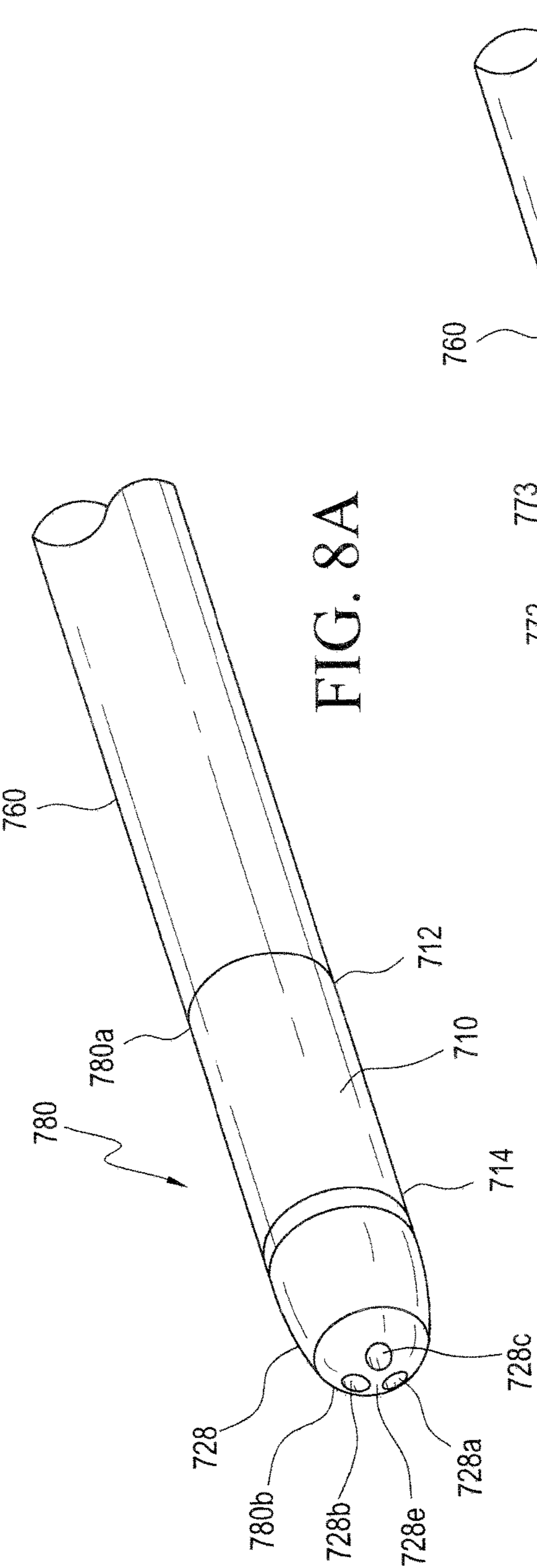


FIG. 7A

FIG. 7B



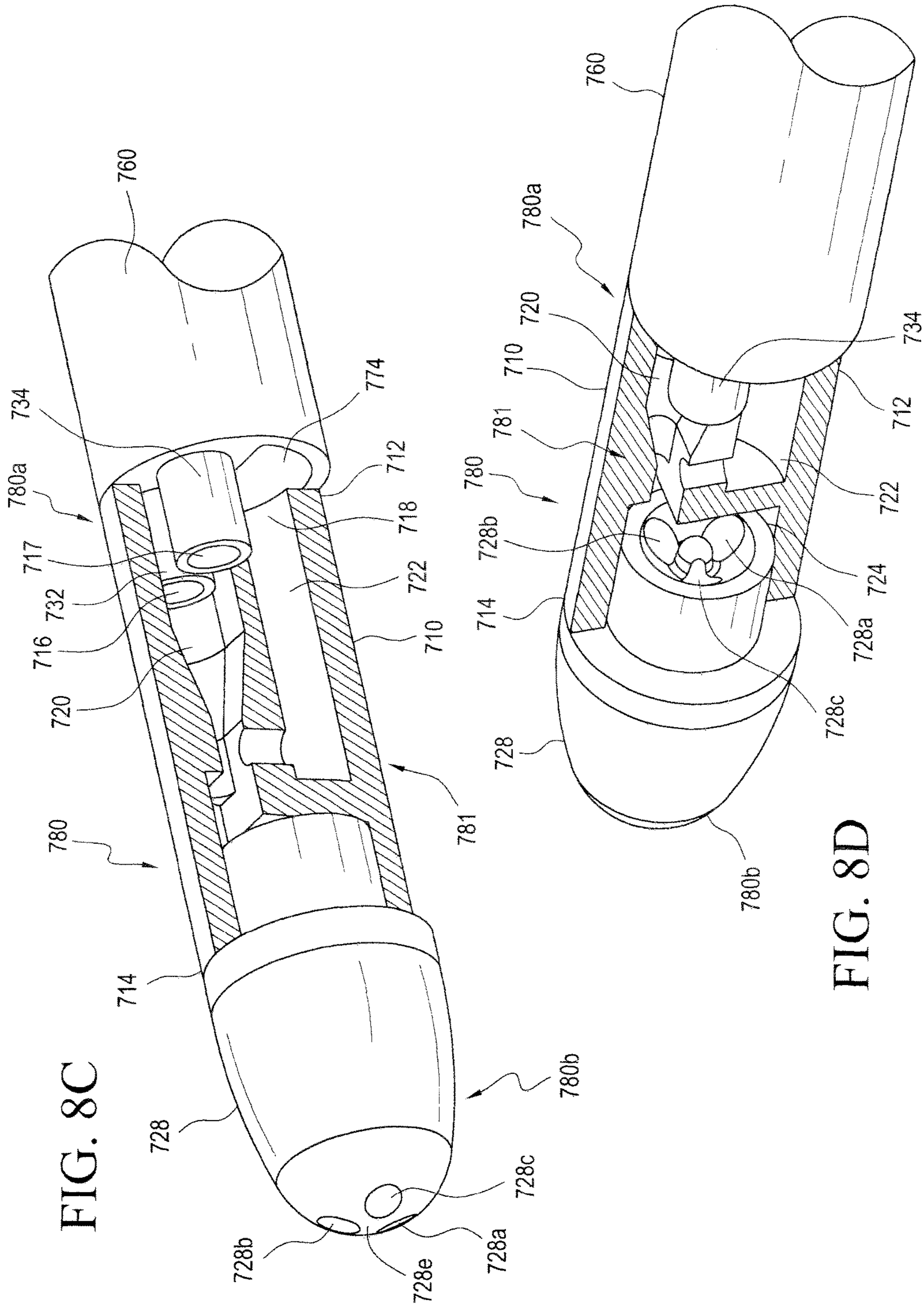


FIG. 8C

FIG. 8D

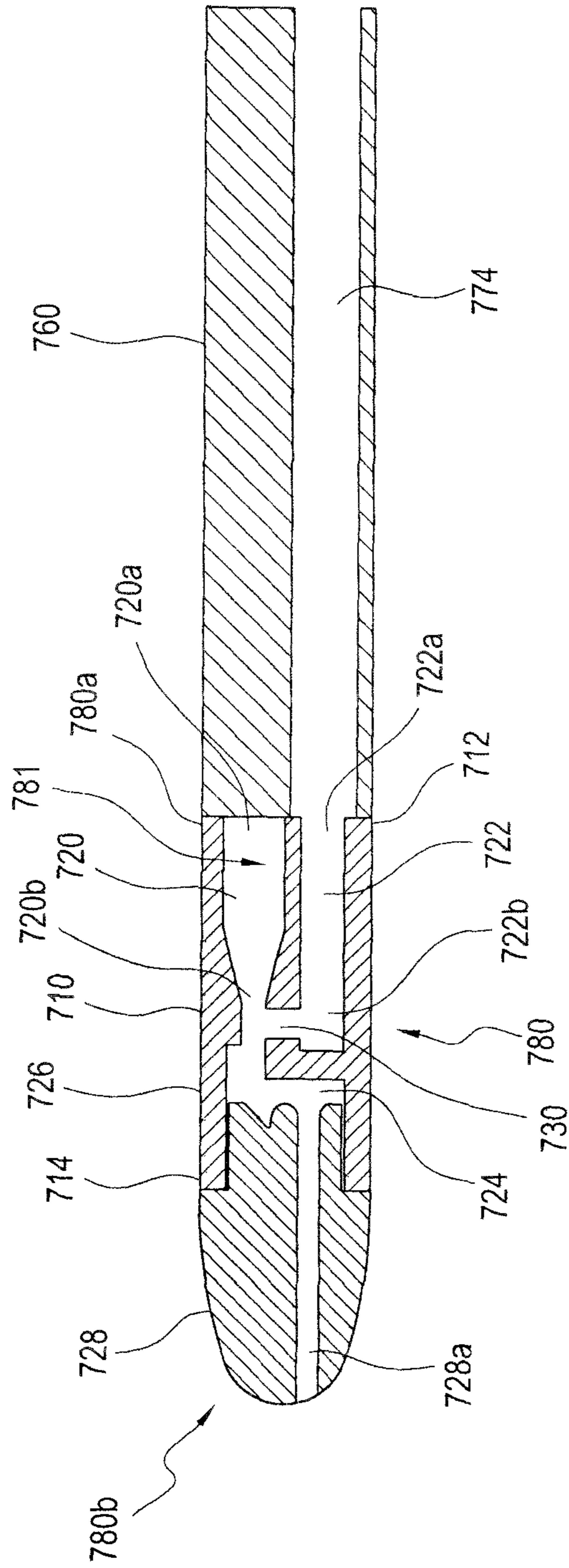
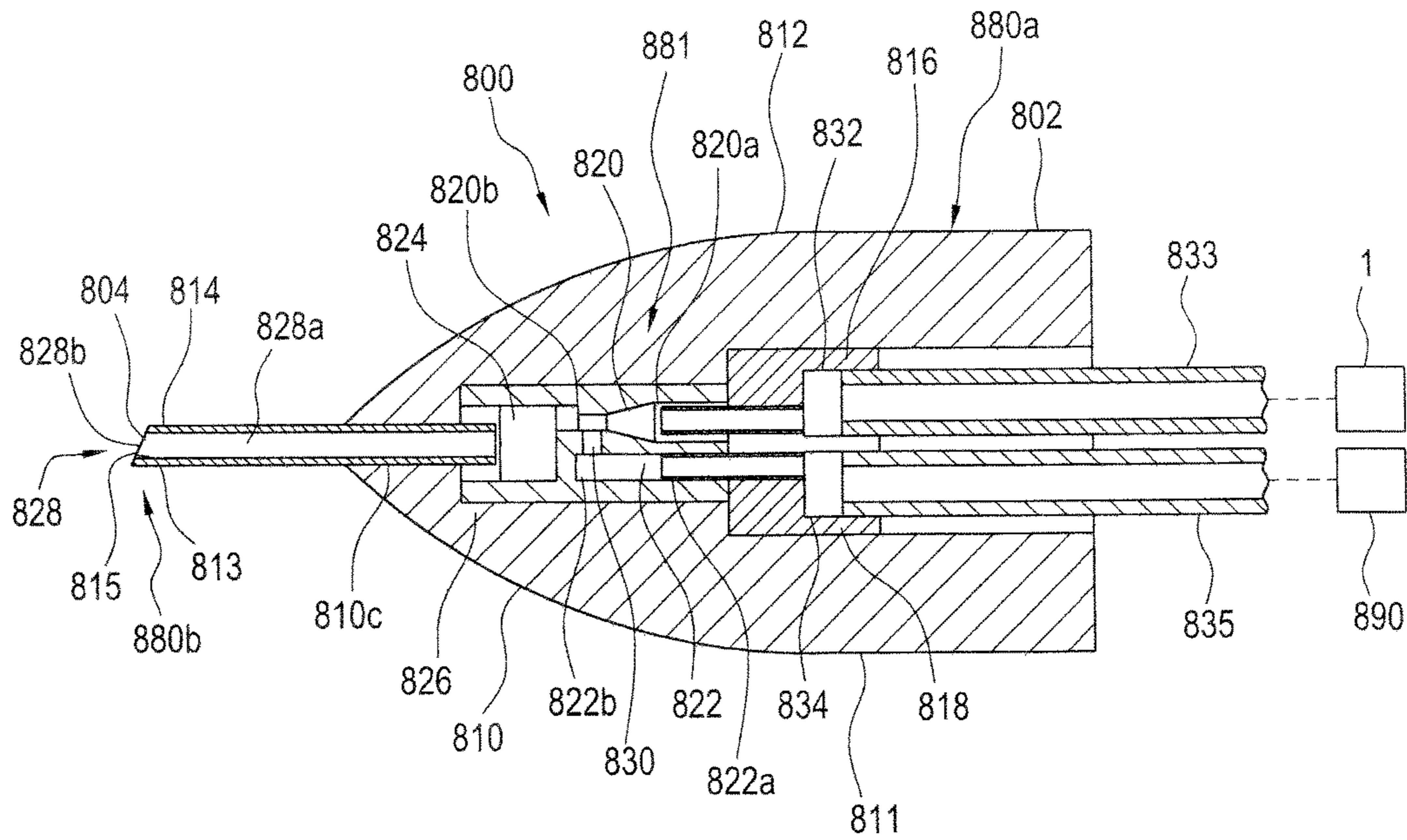
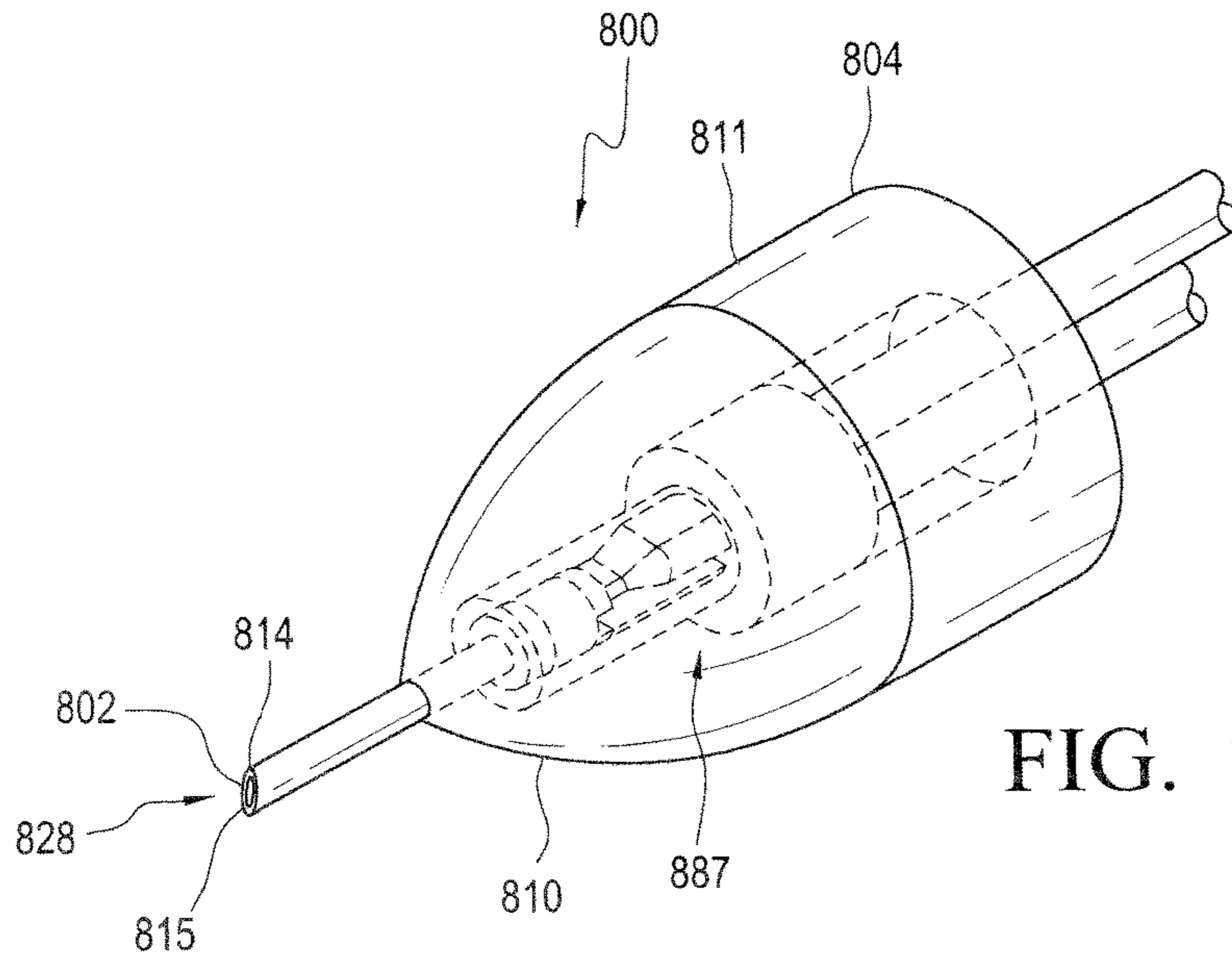


FIG. 8E



1

**DELIVERY SYSTEM AND METHOD FOR
THE EFFECTIVE AND RELIABLE
DELIVERY OF CONTROLLED AMOUNTS
OF A MEDICAL FLUID**

CROSS REFERENCE TO RELATED
APPLICATION

This application is a continuation in part of U.S. patent application Ser. No. 15/053,530, entitled "APPARATUS AND METHOD FOR PRODUCING CO₂ ENRICHED MEDICAL FOAM," filed Feb. 25, 2016, which is currently pending, which claims the benefit of U.S. Provisional Patent Application Ser. No. 62/121,827, entitled "CATHETER FOR PRODUCING CO₂ ENRICHED MEDICAL FOAM," filed Feb. 27, 2015, and this application is a continuation in part of U.S. patent application Ser. No. 15/053,530, filed Feb. 25, 2016, which is currently pending, which is a continuation-in-part of U.S. patent application Ser. No. 14/509,459, entitled "APPARATUS AND PROCESS FOR PRODUCING CO₂ ENRICHED MEDICAL FOAM," filed Oct. 8, 2014, which is now U.S. Pat. No. 9,744,342, which is a continuation of U.S. patent application Ser. No. 13/068,680, entitled "APPARATUS AND PROCESS FOR PRODUCING CO₂ ENRICHED MEDICAL FOAM," filed May 17, 2011, which is now U.S. Pat. No. 8,876,749, which is a continuation-in-part of U.S. patent application Ser. No. 12/652,845, entitled "PORTABLE MEDICAL GAS DELIVERY SYSTEM," filed Jan. 6, 2010, which is abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 12/210,368, entitled "PORTABLE MEDICAL FOAM APPARATUS," filed Sep. 15, 2008, which is abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 11/945,674, entitled "PORTABLE EVAPORATIVE SNOW APPARATUS," filed Nov. 27, 2007, which is now U.S. Pat. No. 7,543,760, which claims the benefit of U.S. Provisional Patent Application Ser. No. 60/867,323, entitled "PORTABLE EVAPORATIVE SNOW APPARATUS," filed Nov. 27, 2006, the disclosures of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an apparatus and process for producing an enriched medical suspension of a sclerosant or other chemical medical solution, for example, polidocanol.

2. Description of the Related Art

The present invention utilizes the Venturi effect to produce an enriched medical suspension of a sclerosant or other chemical medical solution, for example, polidocanol for use in various applications. As those skilled in the art will appreciate, polidocanol is used as a sclerosant to treat varicose veins by causing fibrosis inside varicose veins, occluding the lumen of the vessel, and reducing the appearance of the varicosity. Polidocanol damages the cell lining of blood vessels. The damage to the cell lining causes the blood vessels to close. These vessels are ultimately replaced. The apparatus of the present invention is simple to manufacture and use because it does not require an impeller and incorporated fan in order to create and dispense the enriched medical suspension of polidocanol.

The Venturi effect is an example of Bernoulli's principle, in the case of incompressible fluid flow through a tube or pipe with a constriction in it. The fluid velocity must increase through the constriction to satisfy the equation of continuity, while its pressure must decrease due to conser-

2

vation of energy; the gain in kinetic energy is supplied by a drop in pressure or a pressure gradient force.

The limiting case of the Venturi effect is choked flow, in which a constriction in a pipe or channel limits the total flow rate through the channel because the pressure cannot drop below zero in the constriction. Choked flow is used to control the delivery rate of water and other fluids through spigots and other types of valves. The portable apparatus of the present invention utilizes a source of pressurized medical fluid, to produce the desired pressure and flow for the effective creation of an enriched medical suspension.

SUMMARY OF THE INVENTION

The present invention provides for a novel apparatus for producing an enriched medical suspension of a sclerosant or other chemical medical solution, for example, polidocanol, as well as a process for utilizing such enriched medical suspension in medical treatment, in particular, sclerotherapy via the application of polidocanol. One embodiment of the present invention features an apparatus for producing and delivering an enriched medical suspension of a sclerosant or other chemical medical solution comprising (i) a suspension delivery catheter including a syringe containing a of a sclerosant or other chemical medical solution, a dual lumen catheter and a Venturi-agitating tip assembly; and (ii) a compressed medical fluid unit having at least one container of pressurized sclerosant or other chemical medical solution.

The pressurized medical fluid is preferably polidocanol. However, it is appreciated other suitable pressurized medical fluids may be used in accordance with the present invention. The pressurized polidocanol is contained in a syringe placed under pressure under the control of a medical practitioner or an automated syringe compression mechanism as is known in the art.

The Venturi-agitating tip assembly includes a novel arrangement by which pressurized sclerosant or other chemical medical solution enters a second end of the Venturi-agitating tip assembly through a fluid inlet. The resultant pressure produced within the Venturi-agitating tip assembly draws a medical solution of sclerosant or other chemical medical solution into the interior of the Venturi-agitating tip assembly through a second inlet. The pressurized sclerosant or other chemical medical solution and the medical solution of sclerosant or other chemical medical solution are mixed together to form an enriched medical suspension of sclerosant or other chemical medical solution that continues to travel towards the first end of the Venturi-agitating tip assembly where the enriched medical suspension of sclerosant or other chemical medical solution is sprayed upon the inner lumen of a vessel for the purpose of sclerotherapy.

The present invention also relates to methods of medical treatments. In one embodiment the invention is a method for providing an enriched medical suspension of sclerosant or other chemical medical solution applying such enriched medical suspension to the vascular system comprising the steps of: (i) providing a portable medical fluid apparatus; (ii) providing a container (for example, a syringe) with a medical solution of sclerosant or other chemical medical solution, the container having an entrance, an exit and a release means regulating the exit; (iii) attaching a medically acceptable directional device from the apparatus to the entrance of the container; (iv) initiating an actuator of the apparatus to release the pressurized medical fluid of sclerosant or other chemical medical solution; (v) activating the release mechanism to produce an enriched medical suspension of sclerosant or other chemical medical solution; and (vi) applying

the enriched medical suspension of sclerosant or other chemical medical solution to a predetermined vascular location via a catheter or needle.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects, features and advantages will occur from the following description of a preferred embodiment and the accompanying drawings.

FIG. 1 is a schematic of a compressed medical fluid unit in accordance with the present invention.

FIG. 2 is a perspective view of the suspension delivery catheter and a syringe containing a medical solution of sclerosant or other chemical medical solution.

FIG. 3 is a close-up exploded view of the Venturi-agitating tip assembly shown in FIG. 2.

FIGS. 4A, 4B and 4C respectively show a longitudinal cross sectional view, a perspective view and a perspective cross sectional view of a Venturi-agitating tip assembly in accordance with an alternate first embodiment.

FIGS. 5A, 5B, 5C and 5D are respectively a perspective view, a longitudinal cross-sectional perspective view, an exploded view and a lateral cross-sectional view of a Venturi-agitating tip assembly in accordance with an alternate second embodiment.

FIG. 6 is a cross-sectional view of a Venturi-agitating tip assembly in accordance with an alternate third embodiment.

FIGS. 7A and 7B are respectively a longitudinal cross-sectional view and a lateral cross-sectional view of a Venturi-agitating tip assembly in accordance with an alternate fourth embodiment;

FIGS. 8A, 8B, 8C, 8D and 8E are respectively a perspective view, an exploded view, a front partial cross-sectional view, a rear partial cross-sectional view and a lateral cross-sectional view in accordance with a fifth embodiment;

FIGS. 9A and 9B respectively show a perspective view and a cross-sectional view of a Venturi-agitating tip assembly in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The detailed embodiments of the present invention are disclosed herein. It should be understood, however, that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, the details disclosed herein are not to be interpreted as limiting, but merely as a basis for teaching one skilled in the art how to make and/or use the invention.

Referring to the various figures and embodiments, the medical fluid suspension generating apparatus for performing medical procedures includes a Venturi-agitating tip assembly composed of a multi-channel arrangement at a proximal first end thereof and a tip at a distal second end thereof. The apparatus also includes a compressed medical fluid unit fluidly connected to the multi-channel arrangement at a proximal first end of the Venturi-agitating tip assembly and a medical solution fluidly connected to the multi-channel arrangement at a proximal first end of the Venturi-agitating tip assembly. Pressurized sclerosant or other chemical medical solution, from the compressed medical fluid unit, and the medical solution of sclerosant or other chemical medical solution are combined within the Venturi-agitating tip assembly in a manner generating an enriched medical suspension that is ultimately dispensed from the suspension delivery apparatus. A method in accordance with the apparatus is also disclosed. Through the use of the

present medical fluid suspension generating apparatus procedures may be performed without the use of tumescent anesthesia, thereby alleviating discomforting for patients and simplifying procedures to medical practitioners.

With reference to FIG. 1 the integrated compressed medical fluid unit 1 is disclosed. The integrated compressed medical fluid unit 1 includes a compressible syringe 12 containing sclerosant or other chemical medical solution for dispensing from an outlet 20 of the syringe 12. The syringe 12 includes a one-way valve 22 at its outlet 20 to ensure that sclerosant or other chemical medical solution from the syringe 12 only flows out of the syringe 12.

With reference to FIG. 2, a suspension delivery catheter 2 features a dual lumen catheter 260 connecting a Venturi-agitating tip assembly 280 to pressurized medical sclerosant or other chemical medical solution from the compressed medical fluid unit 1 and a medical solution of sclerosant or other chemical medical solution from a syringe 290. The syringe 290 includes a one-way valve 291 at its outlet to ensure that sclerosant or other chemical medical solution from the syringe 290 only flows out of the syringe 290. The suspension delivery catheter 2 includes a first end (or distal end) 262 having the Venturi-agitating tip assembly 280 and a second end (or proximal end) 264 to which the compressed medical fluid unit 1 and the medical solution of sclerosant or other chemical medical solution are fluidly connected for the passage of pressurized medical sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution. As will be appreciated based upon the following disclosure, a dual lumen catheter 260 is connected to the Venturi-agitating tip assembly by securing a medical fluid hose inlet 230 and a suspension delivery line 225 of the Venturi-agitating tip assembly 280 to a first lumen 272 and a second lumen 274 of the dual lumen catheter 260, respectively. The provision of the Venturi-agitating tip assembly 280 at the very end of the catheter allows for the mixing of pressurized medical sclerosant or other chemical medical solution and the medical solution of sclerosant or other chemical medical solution immediately adjacent the discharge point.

A micro hose 256 connects the compressed medical fluid unit 1 to the first lumen 272 of the dual lumen catheter 260 at a proximal first end 266 thereof for the transmission of the pressurized medical sclerosant or other chemical medical solution from compressed medical fluid unit 1 to the Venturi-agitating tip assembly 280. As such, pressurized medical sclerosant or other chemical medical solution leaving the compressed medical fluid unit 1 via the outlet air port 25 enters the first lumen 272 of the dual lumen catheter 260 via micro hose 256. After passing through the first lumen 272 of the dual lumen catheter 260, the pressurized medical sclerosant or other chemical medical solution passes through medical fluid hose inlet 230 of the Venturi-agitating tip assembly 280 and enters the Venturi-agitating tip assembly 280 of the suspension delivery catheter 2. As will be explained below in greater detail, the medical fluid suspension of sclerosant or other chemical medical solution generated at the Venturi-agitating tip assembly 280 is directly applied to a vein or artery (if not using a sclerosant but using other chemical medical solutions, for example, thrombolytics, cancer drug administration, etc.) requiring treatment with the medical fluid of sclerosant or other chemical medical solution.

As to the connection of the medical solution of sclerosant or other chemical medical solution to the suspension delivery catheter 2, the medical solution of sclerosant or other chemical medical solution is delivered to the second lumen

274 of the dual lumen catheter 260 at the proximal first end 266 thereof, and ultimately to the Venturi-agitating tip assembly 280, via a container, in particular, a syringe 290, connected to the second lumen 274 of the dual lumen catheter 260 by a supply line 216. As mentioned above, the syringe 290 includes a one-way valve 291 at its outlet to ensure that sclerosant or other chemical medical solution from the syringe 290 only flows out of the syringe 290, preventing reflux back into the syringe 290 or the compressible syringe 12 of the compressed medical fluid unit 1. After passing through the second lumen 274 of the dual lumen catheter 260, the medical solution of sclerosant or other chemical medical solution from the syringe 290 travels into the solution delivery line 225 of the Venturi-agitating tip assembly 280 where it is combined with pressurized medical sclerosant or other chemical medical solution from the pressurized medical fluid unit 1 to form an enriched medical suspension of sclerosant or other chemical medical solution.

As shown in FIGS. 2 and 3, and as briefly discussed above, the Venturi-agitating tip assembly 280 includes a proximal first end 282 and a distal second end 284. The Venturi-agitating tip assembly 280 includes an upper chamber 240 at the distal second end 284 of the Venturi-agitating tip assembly 280 and a lower chamber 235 at the proximal first end 282 of the Venturi-agitating tip assembly 280, wherein a distal second end 269 of the dual lumen catheter 260 is fluidly coupled to the lower chamber 235 at the proximal first end 282 of the Venturi-agitating tip assembly 280. The upper chamber 240 and the lower chamber 235 are separated by a wall 237 having an aperture 239 formed therein allowing for the passage of pressurized medical sclerosant or other chemical medical solution released in the lower chamber 235 to pass into the upper chamber 240.

The suspension delivery line 225 passes through the lower chamber 235 and has an outlet 220 for delivering the medical solution of sclerosant or other chemical medical solution into the upper chamber 240. The medical solution of sclerosant or other chemical medical solution is delivered to the suspension delivery line 225 via the syringe 290 and the dual lumen catheter 260. More particularly, the medical solution of sclerosant or other chemical medical solution from the syringe 290 travels through the second lumen 274 of the dual lumen catheter 260 and into the solution delivery line 225 when pressurized medical sclerosant or other chemical medical solution enters the Venturi-agitating tip assembly 280 through the inlet 230 after being actuated and released from the compressed medical fluid unit 1. The pressurized medical sclerosant or other chemical medical solution entering the Venturi-agitating tip assembly 280 imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in the syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through the supply line 216, through the second lumen 274 of the dual lumen catheter 260, and into the solution delivery line 225 due to the Venturi effect. The syringe plunger 290p is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290. Pressurized medical sclerosant or other chemical medical solution traveling from the lower chamber 235 of the Venturi-agitating tip assembly 280 to the upper chamber 240 of the Venturi-agitating tip assembly 280 via aperture 239 in the wall 237 creates negative pressure inside the Venturi-agitating tip assembly 280, such that the medical solution of sclerosant or other chemical medical solution exiting the outlet 220 of the solution delivery line 225 mixes with pressurized medical sclerosant or other chemical medical

solution in the solution delivery line 225 and ultimately forms an enriched medical suspension of sclerosant or other chemical medical solution that is sprayed upon the inner lumen of a vessel via the spray tip 215. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 280 and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end 284 of the Venturi-agitating tip assembly 280 as a spray and onto the inner lumen of a vessel.

It is appreciated various tip assemblies and enriched medical suspension generating structures may be employed in accordance with the present invention. In accordance with a first alternate embodiment as shown with reference to FIGS. 4A-4C, the Venturi-agitating tip assembly 380 employs a Venturi arrangement with a mixing chamber 324. The Venturi-agitating tip assembly 380 has a proximal first end 380a and a distal second end 380b. The Venturi-agitating tip assembly 380 includes a hollow cylindrical elongated body 310 having a proximal first end 312, which coincides with the proximal first end 380a of the Venturi-agitating tip assembly 380, and a distal second end 314. The proximal first end 380a of the Venturi-agitating tip assembly 380 includes a multi-channel arrangement 381 including first and second inputs 316, 318 for attachment to the dual lumen catheter 360. The first and second inputs 316, 318 respectively lead to a first channel 320 and a second channel 322 of the multi-channel arrangement 381 of the Venturi-agitating tip assembly 380. The first and second channels 320, 322 lead to, and are in fluid communication with, a mixing chamber 324 (which also forms part of the multi-channel arrangement 381) located in the central portion 326 of the Venturi-agitating tip assembly 380, that is, between the proximal first end 380a and the distal second end 380b. Located at the distal second end 380b of the Venturi-agitating tip assembly 380, and secured to the distal second end 414 of the elongated body 310, is a spray tip 328 directing the enriched medical suspension of sclerosant or other medical chemical solutions in a spray pattern onto the inner lumen of a vessel.

The first channel 320 and the second channel 322 are interconnected in a manner creating a Venturi effect causing the pressurized medical sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second channel 322 and into the mixing chamber 324. This is achieved by providing with the first channel 320 with a reduced diameter as it extends from the proximal first end 312 of the elongated body 310 (that is, the first end 320a of the first channel 320) to the central portion 326 of the Venturi-agitating tip assembly 380 (that is, the second end 320b of the first channel 320). In accordance with a preferred embodiment, the diameter of the first channel 320 decreases from a diameter of 0.038 inches adjacent the proximal first end 312 of the elongated body 310 to a diameter of 0.017 inches adjacent the mixing chamber 324.

As mentioned above, the second channel 322 is in fluid communication with the first channel 320. This is achieved by the provision of a transverse channel 330 connecting the second end 320b of the first channel 320 with the second end 322b of the second channel 322. In particular, the second channel 322 includes a first end 322a adjacent the proximal first end 312 of the elongated body 310 and a second end 322b adjacent the mixing chamber 324 (although not directly in fluid communication with the mixing chamber

324) and the transverse channel 330. In accordance with a preferred embodiment, the diameter of the second channel 322 is 0.031 inches and remains consistent as it extends from the first end 322a thereof to the second end 322b thereof.

The first lumen 372 of a dual lumen catheter 360 supplies the pressurized sclerosant or other chemical medical solution and the second lumen 374 supplies the medical solution of sclerosant or other chemical medical solution. As such, the first lumen 372 is connected to, and in fluid communication with, the first channel 320 of the Venturi-agitating tip assembly 380 and the second lumen 374 is connected to, and in fluid communication with, the second channel 322 of the Venturi-agitating tip assembly 380. In practice, and as described above in conjunction with the prior embodiment, the medical solution of sclerosant or other chemical medical solution from the syringe 290 travels through the second lumen 374 of the dual lumen catheter 360 and into the second channel 322 when pressurized sclerosant or other chemical medical solution enters the first channel 320 and passes the transverse channel 330 into the mixing chamber 324 after being actuated and released from the compressed medical fluid unit 1. The pressurized sclerosant or other chemical medical solution entering the Venturi-agitating tip assembly 380 imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in the syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through the second channel 322, through the second lumen 374 of the dual lumen catheter 360, and into the mixing chamber 324 due to the Venturi effect. The medical solution of sclerosant or other chemical medical solution and the pressurized sclerosant or other chemical medical solution are then mixed within the mixing chamber 324 to form an enriched medical suspension of sclerosant or other chemical medical solution. The syringe plunger 290p is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290.

The pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the mixing chamber 324 are then forced through the spray tip 328 from which the enriched medical suspension of sclerosant or other chemical medical solution is sprayed upon the inner lumen of a vessel. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 380 and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end 384 of the Venturi-agitating tip assembly 380 as a spray and onto the inner lumen of a vessel.

In accordance with a second embodiment as shown with reference to FIGS. 5A-5D, a Venturi-agitating tip assembly 480 employs a spray tip 428 in conjunction with a multi-channel arrangement 481 where the pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution are mixed and forced through the spray tip 428. The Venturi-agitating tip assembly 480 includes a proximal first end 480a and a distal second end 480b. The Venturi-agitating tip assembly 480 includes a hollow cylindrical elongated body 410 having a proximal first end 412, which coincides with the proximal first end 480a of the Venturi-agitating tip assembly 480, and a distal second end 414. The Venturi-agitating tip assembly 480 is adapted for use with a dual lumen catheter 460, in particular a dual lumen catheter having concentric lumens, wherein the outer first lumen 472 is annular shaped for the

passage of pressurized sclerosant or other chemical medical solution (and has an outer diameter of 0.092 inches at the outer wall thereof and an inner diameter of 0.042 inches at the inner wall thereof) and the inner second lumen 474 is circular shaped for the passage of the medical solution of sclerosant or other chemical medical solution (and has a diameter of 0.030 inches). The inner second lumen 474 is supported within the outer first lumen 472 by first and second radially extending rib members 473a, 473b (each having a thickness of 0.006 inches) that extend from the outer surface of the second lumen 474 to the inner surface of the outer first lumen 472. In this way the outer first lumen 472 is divided into first and second semicircular passageways 475a, 475b.

The proximal first end 480a of the Venturi-agitating tip assembly 480, in particular, the proximal first end 412 of the elongated body 410 is formed with two projections 432, 434 shaped and dimensioned for engagement within the outer first lumen 472 of the catheter 460 in a manner blocking a substantial portion of the outer first lumen 472. The two projections 432, 434 are arcuate members shaped and dimensioned to respectively block substantial portions of the first and second semicircular passageways 475a, 475b while creating four small passageways 436, each of approximately 0.031 inches (along the Y-axis as shown in FIG. 5D) by 0.050 inches (along the X-axis as shown in FIG. 5D) for the passage of pressurized sclerosant or other chemical medical solution therethrough. The four small passageways 436 are defined by spaces existing between the edges of the arcuate members 432, 434 and the first and second radially extending rib members 473a, 473b.

The remainder of the Venturi-agitating tip assembly 480 includes a central mixing chamber 424 that is in fluid communication with the second lumen 474 and the four small passageways 436 feeding pressurized sclerosant or other chemical medical solution from the first lumen 472. Secured to, and closing off, the second end 414 of the elongated body 410 is a spray tip 428, which is thereby positioned at the distal second end 480b of the Venturi-agitating tip assembly 480. Attachment of the spray tip 428 to the elongated body 410 is achieved by providing the spray tip 428 with a projection 438 that seats within the opening at the second end 414 of the elongated body 410.

The first lumen 472 and the second lumen 474 are interconnected in a manner causing the pressurized sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second lumen 474 and into the mixing chamber 424. In practice, the medical solution of sclerosant or other chemical medical solution from the syringe 290 travels through the second lumen 474 of the dual lumen catheter 460 and into the mixing chamber 424 when pressurized medical sclerosant or other chemical medical solution passes through the four small passageways 436 and enters the mixing chamber 424 (where the medical solution of sclerosant or other chemical medical solution from the syringe 290 and the pressurized medical sclerosant or other chemical medical solution mix to form an enriched medical suspension of sclerosant or other chemical medical solution) after being actuated and released from compressed medical fluid unit 1. The pressurized sclerosant or other chemical medical solution entering the mixing chamber 424 imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through the second lumen 474 and into the mixing chamber 424. The syringe plunger 290p

is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290.

The pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the mixing chamber 424 are then forced through the spray tip 428 from which an enriched medical suspension of sclerosant or other chemical medical solution is sprayed upon the inner surface of a lumen. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 480 and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end 484 of the Venturi-agitating tip assembly 480 as a spray and onto the inner lumen of a vessel.

In accordance with a third embodiment as shown with reference to FIG. 6, a Venturi-agitating tip assembly 580 is composed solely of a porous sintered material tip 528 shaped and dimensioned for attachment to the end of a dual lumen catheter 560, in particular, a dual lumen catheter 560 having concentric lumens, wherein the outer first lumen 572 is annular shaped for the passage of pressurized sclerosant or other chemical medical solution (and has an outer diameter of 0.092 inches at the outer wall thereof and an inner diameter of 0.042 inches at the inner wall thereof) and the inner second lumen 574 is circular shaped for the passage of the medical solution of sclerosant or other chemical medical solution (and has a diameter of 0.030 inches). The inner second lumen 574 is supported within the outer first lumen 572 by first and second radially extending rib members (as shown in FIGS. 5C and 5D) that extend from the outer surface of the second lumen 574 to the inner surface of the outer first lumen 572. In this way the outer first lumen 572 is divided into first and second semicircular passageways 575a, 575b.

The proximal first end 512 of the sintered material tip 528 is formed with a circular recess 550 shaped and dimensioned to correspond with the outlet of the first lumen 572 at the distal end of the dual lumen catheter 560. A longitudinally extending projection 552 extends from the center of the proximal first end 512 and is shaped and dimensioned for frictional placement within the central second lumen 574 so as to close off (with the exception of the porous nature of the spray tip) the second lumen 574. The attachment of the sintered material tip 528 at the distal end of the dual lumen catheter 560 is achieved by the provision of a shrink wrap member 554 at the junction of the dual lumen catheter 560 with the sintered material tip 528.

The first lumen 572 and the second lumen 574 are interconnected via the sintered material tip 528 in a manner causing the pressurized sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second lumen 574 and into the sintered material tip 528 where they mix to form an enriched medical suspension of sclerosant and other chemical medical solution and are ultimately forced through the sintered material tip 528. In practice, the medical solution of sclerosant or other chemical medical solution from syringe 290 travels through the second lumen 574 of the dual lumen catheter 560 and into the sintered material tip 528 when pressurized sclerosant or other chemical medical solution passes through the first lumen 572 and into the sintered material tip 528. The pressurized sclerosant or other chemical medical solution entering the sintered material tip 528 imparts negative Venturi pressure on the

medical solution of sclerosant or other chemical medical solution in syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through the second lumen 574 and into the sintered material tip 528. The syringe plunger 290p is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290.

The pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the sintered material tip 528 are then forced through the sintered material tip 528 where an enriched medical suspension of sclerosant or other chemical medical solution forms on the exterior surface 528a of the sintered material tip 528. In particular, the force of the pressurized sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 580 and exiting through the sintered material tip 528 lifts the enriched medical suspension of sclerosant or other chemical medical solution outward from the exterior surface 528a of the sintered material tip 528 and projects the enriched medical suspension of sclerosant or other chemical medical solution from the second end 580b of the Venturi-agitating tip assembly 580.

In accordance with a fourth embodiment as shown with reference to FIGS. 7A and 7B, a Venturi-agitating tip 680 employs a spray tip 628 in conjunction with a multi-channel arrangement 681 where the pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution are mixed to form an enriched suspension of sclerosant or other chemical medical solution and forced through the spray tip 628. The Venturi-agitating tip assembly 680 includes a proximal first end 680a and a distal second end 680b. The Venturi-agitating tip assembly 680 includes a cylindrical hollow elongated body 610 having a proximal first end 612, which coincides with the proximal first end 680a of the Venturi-agitating tip assembly 680, and a distal second end 614, which coincides with the distal second end 680b of the Venturi-agitating tip assembly 680. The Venturi-agitating tip assembly 680 is adapted for use with a dual lumen catheter 660, in particular a dual lumen catheter having concentric lumens, wherein the outer first lumen 672 is annular shaped for the passage of pressurized sclerosant or other chemical medical solution (and has an outer diameter of 0.092 inches at the outer wall thereof and an inner diameter of 0.042 inches at the inner wall thereof) and the inner second lumen 674 is circular shaped for the passage of the medical solution of sclerosant or other chemical medical solution (and has a diameter of 0.030 inches). The inner second lumen 674 is supported within the outer first lumen 672 by first and second radially extending rib members (as shown in FIGS. 5C and 5D) that extend from the outer surface of the second lumen 674 to the inner surface of the outer first lumen 672. In this way the outer first lumen 672 is divided into first and second semicircular passageways 675a, 675b.

The proximal first end 612 of the elongated body 610 at the proximal first end 680a of the Venturi-agitating tip assembly 680 includes an end wall 661 (created by adhesive injected to limit flow from the first lumen 672) with two projecting channels 662a, 662b (each with a diameter of 0.015 inches) shaped and dimensioned for engagement with the first and second semicircular passageways 675a, 675b. The end wall 660 of the proximal first end 612 of the elongated body 610 is also provided with a central aperture 664 shaped and dimensioned for alignment with the second lumen 674. The remainder of the proximal first end 612 of

the elongated body 610 is closed off thus limiting and controlling the flow of materials into the central mixing chamber 624.

The remainder of the Venturi-agitating tip assembly 680 includes a central mixing chamber 624 that is in fluid communication with the second lumen 674 and the two projecting channels 662a, 662b feeding pressurized sclerosant or other chemical medical solution from the first lumen 672. As a result, and as will be explained below in greater detail the medical solution of sclerosant or other chemical medical solution and the pressurized medical sclerosant or other chemical medical solution are mixed within the mixing chamber 624 to form an enriched medical suspension of sclerosant or other chemical medical solution. Secured to, and closing off, the second end 614 of the elongated body 610 is a spray tip 628, which is thereby positioned at the distal second end 680b of the Venturi-agitating tip assembly 680.

The first lumen 672 and the second lumen 674 are interconnected in a manner causing the pressurized sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second lumen 674 and into the mixing chamber 624. In practice, the medical solution of sclerosant or other chemical medical solution from the syringe 290 travels through the second lumen 674 of the dual lumen catheter 660 and into the mixing chamber 624 when pressurized sclerosant or other chemical medical solution passes through the first and second projecting channels 662a, 662b and enters the mixing chamber 624 after being actuated and released from the compressed medical fluid unit 1. The pressurized sclerosant or other chemical medical solution entering the mixing chamber 624 imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in the syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through second lumen 674 and into the mixing chamber 624. The syringe plunger 290p is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290.

The pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the mixing chamber 624 is then forced through the spray tip 628 from which an enriched medical suspension of sclerosant or other chemical medical solution is sprayed. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 680 and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end 684 of the Venturi-agitating tip assembly 680 as a spray and onto the inner lumen of a vessel.

In accordance with a fifth embodiment as shown with reference to FIGS. 8A-8E, a Venturi-agitating tip assembly 780 employs a tip 728 in conjunction with a multi-channel arrangement 781 where the pressurized sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution are mixed to form an enriched suspension of sclerosant or other chemical medical solution and forced through the tip 728. The Venturi-agitating tip assembly 780 includes proximal first end 780a and a distal second end 780b. The Venturi-agitating tip assembly 780 includes a hollow cylindrical elongated body 710 having a proximal first end 712, which coincides with the proximal first end 780a of the Venturi-agitating tip assembly

780, and a distal second end 714. The Venturi-agitating tip assembly 780 is adapted for use with a multi-lumen catheter 760, in particular a triple lumen catheter having parallel lumens, wherein the first and second lumens 772, 773 are circular shaped (each with a diameter of 0.039 inches) and are dimensioned for the passage of pressurized sclerosant or other chemical medical solution and the third lumen 774 is semi-circular shaped (with a radius of 0.047 inches) and is dimensioned for the passage of the medical solution of sclerosant or other chemical medical solution.

The proximal first end 712 of the elongated body 710 at the proximal first end 780a of the Venturi-agitating tip assembly 780 includes first, second and third inputs 716, 717, 718 for attachment to the multi-lumen catheter 760. The first and second inputs 716, 717 lead to a first channel 720 and the third input 718 to a second channel 722. As such, the proximal first end 712 of the elongated body 710 at the proximal first end 780a of the Venturi-agitating tip assembly 780 is formed with two circular tubular projections 732, 734, defining the first and second inputs 716, 717. The circular tubular projections 732, 734 (each with an inner diameter of 0.027 inches and an outer diameter of 0.039 inches) are shaped and dimensioned for engagement within the first and second lumens 772, 773 of the catheter 760 in a manner allowing for the flow of fluid from the first and second lumens 772, 773 and into the Venturi-agitating tip assembly 780. The two circular tubular projections 732, 734 are shaped and dimensioned to fit within the first and second lumens 772, 773 while maintaining passageways for the passage of pressurized sclerosant or other chemical medical solution therethrough.

The first and second channels 720, 722 lead to, and are in fluid communication with, a mixing chamber 724 located in the central portion 726 of the Venturi-agitating tip assembly 780, that is, between the proximal first end 712 and the distal second end 714 of the elongated body. Secured to the distal second end 714 of the elongated body 710, and positioned at the distal second end 780b of the Venturi-agitating tip assembly, is a tip 728 having three passageways 728a, 728b, 728c extending from the mixing chamber 724 to the exterior at the distal end of the Venturi-agitating tip assembly 780.

The first channel 720 and the second channel 722 are interconnected in a manner creating a Venturi effect causing the pressurized sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second channel 722 and into the mixing chamber 724. This is achieved by providing the first channel 720 with a reduced diameter (decreasing from 0.038 inches to 0.017 inches) as it extends from the proximal first end 712 of the elongated body 710 (that is, the first end 720a of the first channel 720) to the central portion 726 of the Venturi-agitating tip assembly 780 (that is, the second end 720b of the first channel 720). In accordance with a preferred embodiment, the diameter of the first channel 720 decreases from a diameter of 0.038 inches adjacent the proximal first end 712 of the elongated body 710 to a diameter of 0.017 inches adjacent the mixing chamber 724.

As mentioned above, the second channel 722 is in fluid communication with the first channel 720. This is achieved by the provision of a transverse channel 730 connecting the second end 720b of the first channel 720 with the second end 722b of the second channel 722. In particular, the second channel 722 includes a first end 722a adjacent the proximal first end 712 of the elongated body 710 and a second end 722b adjacent the mixing chamber 724 (although not directly in fluid communication with the mixing chamber

724) and the transverse channel 730. In accordance with a preferred embodiment, the diameter of the second channel 722 is 0.047 inches and remains consistent as it extends from the first end 722a thereof to the second end 722b thereof.

The first and second lumens 772, 773 supply the pressurized sclerosant or other chemical medical solution and the third lumen 774 supplies the medical solution of sclerosant or other chemical medical solution. As such, the first and second lumens 772, 773 are connected to, and in fluid communication, with the first channel 720 of the Venturi-agitating tip assembly 780 and the third lumen 774 is connected to, and in fluid communication, with the second channel 722 of the Venturi-agitating tip assembly 780. In practice, the medical solution of sclerosant or other chemical medical solution from syringe 290 travels through third lumen 774 of multi-lumen catheter 760 and into the second channel 722 when pressurized sclerosant or other chemical medical solution enters the first channel 720 and passes the transverse channel 730 (having a size of 0.020 inches) into the mixing chamber 724 after being actuated and released from compressed medical fluid unit 1. The pressurized sclerosant or other chemical medical solution entering the Venturi-agitating tip assembly 780 imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in syringe 290 and draws the medical solution of sclerosant or other chemical medical solution from the syringe 290 through second channel 722, through the third lumen 774 of the dual lumen catheter 760, and into the mixing chamber 724 due to the Venturi effect. The syringe plunger 290p is used to regulate or stop flow of medical solution of sclerosant or other chemical medical solution from the syringe 290.

The pressurized medical sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the mixing chamber 724 form an enriched medical suspension of sclerosant or other chemical medical solution that is then forced through the passageways 728a-c of the spray tip 728. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly 780 and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end 784 of the Venturi-agitating tip assembly 780 as a spray and onto the inner lumen of a vessel.

In accordance with the various embodiments described above, the enriched medical suspension of sclerosant or other chemical medical solution then exiting the Venturi-agitating tip assembly is directed to a vessel requiring treatment. In accordance with a preferred embodiment, the method for treatment in accordance with the present invention is achieved in the following manner. The first end of the suspension delivery catheter, that is, Venturi-agitating tip assembly is introduced into a diseased/varicose vein requiring treatment such that the first end of Venturi-agitating tip assembly is positioned beyond the section of vein requiring treatment.

The second end of suspension delivery catheter is coupled to the compressed medical fluid unit and the syringe. At this point, compressed medical fluid unit is actuated to supply pressurized medical sclerosant or other chemical medical solution to the suspension delivery catheter and an enriched medical suspension of sclerosant or other chemical medical solution is produced at Venturi-agitating tip assembly of suspension delivery catheter. The enriched medical suspension of sclerosant or other chemical medical solution sprays

from the first end of Venturi-agitating tip assembly into the section of vein requiring treatment. As the catheter is withdrawn from the vein, the enriched medical suspension of sclerosant or other chemical medical solution is dribbled into the vein at various segments causing the vein to go into spasm resulting in eventual destruction of the diseased vein. Where the present invention is used in the treatment of the arterial or venous system without the goal of spasm or vessel destruction, the chemical medical solution is sprayed, or otherwise delivered, as required for the procedure being performed.

In accordance with yet another embodiment, the concepts underlying the present invention may be applied in the provision of a medical suspension delivery needle. Such a medical suspension delivery needle would be useful in accessing vessel locations that are inaccessible by the catheter described above. The needle embodiment may also be useful in accessing locations that are limited in length and might not require the use of the suspension delivery catheter described above.

In accordance with such a medical suspension delivery needle embodiment, as shown with reference to FIGS. 9A and 9B, the medical suspension delivery needle 800 has a proximal first end 802, and a distal second end 804. In contrast to the prior embodiments, the medical suspension delivery needle 800 combines the pressurized medical sclerosant or other chemical medical solution and the medical solution of sclerosant or other chemical medical solution at the proximal first end 802 of the medical suspension delivery needle 800 and creates an enriched medical fluid suspension of sclerosant or other chemical medical solution via the inclusion of a porous membrane 815 at the distal second end 804 of the medical suspension delivery needle 800. With this in mind, the medical suspension delivery needle 800 includes a hollow and substantially rigid elongated needle body 810. The needle body 810 includes a needle hub 811 at the proximal first end 812, which coincides with the proximal first end 802 of the medical suspension delivery needle 800, thereof and a sharp beveled edge 813 at the distal second end 814, which coincides with the distal second end 804 of the medical suspension delivery needle 800, thereof. With this in mind, and as will be appreciated based upon the following disclosure, the pressurized medical sclerosant or other chemical medical solution source (that is, the compressed medical fluid unit 1) and the medical solution of sclerosant or other chemical medical solution source (that is, the syringe 290) are coupled to respective first and second inputs 816, 818 found within the needle hub 811 at the proximal end 804 of the medical suspension delivery needle 800.

As with the suspension delivery catheters discussed above, the medical suspension delivery needle 800 employs a spray tip 828 in conjunction with a multi-channel arrangement 881 where the pressurized medical sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution are mixed by the Venturi-agitating tip assembly 880 to form an enriched suspension of sclerosant or other chemical medical solution and forced through the spray tip 828 under the force generated by the Venturi system implemented in accordance with the present invention. The Venturi-agitating tip assembly 880 in accordance with the medical suspension delivery needle 800 of the present embodiment includes the spray tip 828 and the multi-channel arrangement 881 that are separated along the length of the needle body 810. However, the Venturi-agitating tip assembly 880 is integrally formed with the needle body 810 and the Venturi-agitating tip assembly

880 is considered to include a proximal first end **880a** (that coincides with the proximal first end **802** of the suspension delivery needle **800**) and a distal second end **880b** (that coincides with the distal second end **804** of the medical suspension delivery needle **800** and is found in the needle hub **811**). As such, the Venturi-agitating tip assembly **880** includes the hollow cylindrical elongated body **810** of the medical suspension delivery needle **800** as well as the internal flow controlling components discussed herein. As for the needle body **810**, and with the exception of the multi-channel arrangement **881** found in the needle hub **811** at the proximal first end **802** of the medical suspension delivery needle **800**, it is of a single lumen construction and includes a single lumen cannula **810c** along that portion distal to the multi-channel arrangement **881** and the hub **811**.

The multi-channel arrangement **881** found in the needle hub **811** at the proximal first end **880a** of the Venturi-agitating tip assembly **880** includes first and second inputs **816**, **818** for attachment to the pressurized medical sclerosant or other chemical medical solution source (that is, the compressed medical fluid unit **1**) and the medical solution of sclerosant or other chemical medical solution (that is, the syringe **290**). The first input **816** leads to a first channel **820** and the second input **818** leads to a second channel **822**. The proximal first end **880a** of the Venturi-agitating tip assembly **880**, and therefore the proximal first end **812** of the needle body **810**, is formed with two circular tubular female coupling recesses **832**, **834**, defining the first and second inputs **816**, **818**. The coupling recesses **832**, **834** are shaped and dimensioned for fluid coupling with the pressurized medical sclerosant or other chemical medical solution source (that is, the compressed medical fluid unit **1**) and the medical solution of sclerosant or other chemical medical solution (that is, the syringe **290**), for example, via flexible cannulas **833**, **835**, in a manner allowing for the flow of fluid from the compressed medical fluid unit **1** and the syringe **290**), and into the needle body **810**.

The first channel **820** leads to, and is in fluid communication with, a mixing chamber **824** located in the central portion **826** of the Venturi-agitating tip assembly **880**, that is, between the proximal first end **880a** and the distal second end **880b**. Located at the distal second end **880b** is a spray tip **828** having a passageway **828a** extending from the mixing chamber **824** to the exterior at the distal end **880b** of the Venturi-agitating tip assembly **880**.

The first channel **820** and the second channel **822** are interconnected in a manner creating a Venturi effect causing the pressurized medical sclerosant or other chemical medical solution to effectively pull the medical solution of sclerosant or other chemical medical solution through the second channel **822** and into the mixing chamber **824** where the pressurized medical sclerosant or other chemical medical solution and the medical solution of sclerosant or other chemical medical solution mix to form an enriched medical suspension of sclerosant or other chemical medical solution. This is achieved by providing the first channel **820** with a reduced diameter as it extends from the proximal first end **812** of the needle body **810** (that is, the first end **820a** of the first channel **820**) to the central portion **826** of the elongated body **810** (that is, the second end **820b** of the first channel **820**).

As mentioned above, the second channel **822** is in fluid communication with the first channel **820**. This is achieved by the provision of a transverse channel **830** connecting the second end **820b** of the first channel **820** with the second end **822b** of the second channel **822**. In particular, the second channel **822** includes a first end **822a** adjacent the proximal

first end **812** of the elongated body **810** and a second end **822b** adjacent the mixing chamber **824** (although not directly in fluid communication with the mixing chamber **824**) and the transverse channel **830**.

The pressurized medical sclerosant or other chemical medical solution source supplies the pressurized medical sclerosant or other chemical medical solution and the medical solution of sclerosant or other chemical medical solution source supplies the sclerosant or other chemical medical solution. As such, the pressurized medical sclerosant or other chemical medical solution source is connected to, and in fluid communication with, the first channel **820** of the Venturi-agitating tip assembly **880** and the medical solution of sclerosant or other chemical medical solution source is connected to, and in fluid communication with, the second channel **822** of the Venturi-agitating tip assembly **880**. In practice, a syringe **290** containing medical solution of sclerosant or other chemical medical solution is secured to the second input **818** at the proximal first end **802** of the suspension delivery needle **800** via a flexible cannula **833** and the pressurized medical sclerosant or other chemical medical solution from the compressed medical fluid unit **1** is secured to the first input **816** at the proximal first end **802** of the suspension delivery needle **800** via a flexible cannula **835**. The medical solution of sclerosant or other chemical medical solution from the syringe **290** travels through second input **818** and into the second channel **822** when pressurized medical sclerosant or other chemical medical solution enters the first channel **820** and passes the transverse channel **830** into the mixing chamber **824** after being actuated and released from compressed medical fluid unit **1**. The pressurized medical sclerosant or other chemical medical solution entering the Venturi-agitating tip assembly **880** imparts negative pressure on the medical solution of sclerosant or other chemical medical solution in syringe **290** and draws the medical solution of sclerosant or other chemical medical solution from the syringe **290** through second channel **822**, through second input **818** of the medical suspension delivery needle **800**, and into the mixing chamber **824** due to the Venturi effect. The syringe plunger **290p** is used to regulate or stop flow from syringe **290**.

The pressurized medical sclerosant or other chemical medical solution and medical solution of sclerosant or other chemical medical solution mixing in the mixing chamber **824** (to form an enriched medical suspension of sclerosant or other chemical medical solution) are then forced through the remainder of the needle body **810**, in particular, the single lumen portion thereof, and through the spray tip **828** from which the enriched medical suspension of sclerosant or other chemical medical solution is sprayed upon the inner lumen of a vessel. The force of the pressurized medical sclerosant or other chemical medical solution traveling through the Venturi-agitating tip assembly **880** and exiting through the spray tip as part of an enriched medical suspension of sclerosant or other chemical medical solution projects the enriched medical suspension of sclerosant or other chemical medical solution from the distal second end **884** of the Venturi-agitating tip assembly **880** as a spray and onto the inner lumen of a vessel.

It will be appreciated the fluid mechanics of the medical suspension delivery needle embodiment are similar to those of the embodiment discussed with reference to FIGS. **8A-8D**, and the dimensions would therefore be similar.

As the medical suspension delivery needle embodiment shows, the concepts underlying the present invention may be implemented using a needle, that is, a rigid cannula, or a catheter, that is, a flexible cannula. Accordingly, the term

medical suspension delivery cannula should be considered to encompass both those embodiments implemented using a catheter and those embodiments using a needle.

It is appreciated this procedure can be performed under ultrasound guidance or radiograph in order for the physician to control the amount of liquid to mix with the pressurized medical sclerosant or other chemical medical solution to form the enriched medical suspension of sclerosant or other chemical medical solution.

Further to the general method for vein treatment as discussed above, it is contemplated the present suspension delivery catheter may be utilized in the treatment of the great saphenous vein. As those skilled in the art will appreciate, the great saphenous vein is a large, subcutaneous, superficial vein of the leg. It is the longest vein of the body running along the length of the leg. In particular, the great saphenous vein originates from where the dorsal vein of the first digit (that is, the large toe) merges with the dorsal venous arch of the foot. The great saphenous vein extends along the inner portion of the leg until it reaches the common femoral vein in the region of the femoral triangle at the sapheno-femoral junction. Given its size, the great saphenous vein is highly related to vascular issues relating to vein ablation. With this in mind, the present suspension delivery catheter is utilized so as to apply an enriched medical suspension within the great saphenous vein in an effective manner for the treatment and ablation thereof. Where the present invention is used in conjunction with procedures other than treatment of the great saphenous vein as described above, the chemical medical solution is sprayed, or otherwise delivered, as required for the procedure being performed.

With this in mind, the Venturi-agitating tip assembly is introduced into the great saphenous vein. As discussed above, with the first end of the Venturi-agitating tip assembly positioned beyond the section of the great saphenous vein requiring treatment, the second end of the suspension delivery catheter is coupled to the compressed medical fluid unit and the syringe. At this point, the compressed medical fluid unit is actuated to supply pressurized sclerosant or other chemical medical solution to the suspension delivery catheter and an enriched medical suspension of sclerosant or other chemical medical solution is produced at the Venturi-agitating tip of the suspension delivery catheter. The enriched medical suspension of sclerosant or other chemical medical solution sprays from the membrane at the first end of the Venturi-agitating tip assembly into the section of the great saphenous vein requiring treatment. As the enriched medical suspension of sclerosant or other chemical medical solution is permitted to spray, the catheter is withdrawn from the vein and the enriched medical suspension of sclerosant or other chemical medical solution is sprayed into the vein at various segments causing the vein to go into spasms resulting in eventual destruction of the diseased vein. More particularly, and considering a minimal incisional approach at the medial aspect of the knee at the area of the distal end of the great saphenous vein, the suspension delivery catheter is inserted upward toward the sapheno-femoral junction at the proximal end of the great saphenous vein, at the thigh area. Once the Venturi-agitating tip assembly is properly positioned, the enriched medical suspension of sclerosant or other chemical medical solution is produced at the tip of the catheter, it is then deposited in the segments of the vessel of the great saphenous vein at the portion of the vein that will react to the enriched medical suspension of sclerosant or other chemical medical solution and subsequently put the vein segment into spasm. Then, as the suspension delivery catheter is removed, more distal portions of the vein are

caused to spasm and the suspension delivery catheter is withdrawn at the point of insertion at the knee area of the great saphenous vein. In accordance with such a procedure when employing the present suspension delivery catheter, the enriched medical suspension of sclerosant or other chemical medical solution is used to contact the entire lumen of the great saphenous vein.

In addition to the treatment of the great saphenous vein, the present suspension delivery catheter may be used in the treatment of various vascular ailments. The potential treatments that may employ the present suspension delivery catheter include, but are not limited to the following, oncology medical solutions, microbeads, magnetic beads or particles for thrombus treatment, metallic beads or particles for thrombus treatment, embolics, driving drugs through the blood-brain barrier for neurological conditions, driving or delivering TPA (Tissue Plasminogen Activator) for thrombolytic usage, etc.

It is appreciated that where microparticles are used in conjunction with the chemical medical solution, saline may be used with the microparticles, especially in conjunction with the needle embodiment, so as to place the microparticles into suspension. While this detailed description has set forth particularly preferred embodiments of the apparatus of this invention, numerous modifications and variations of the structure of this invention, all within the scope of the invention, will readily occur to those skilled in the art. Accordingly, it is understood that this description is illustrative only of the principles of the invention and is not limitative thereof.

Although specific features of the invention are shown in some of the drawings and not others, this is for convenience only, as each feature may be combined with any and all of the other features in accordance with this invention.

While the preferred embodiments have been shown and described, it will be understood that there is no intent to limit the invention by such disclosure, but rather, it is intended to cover all modifications and alternate constructions falling within the spirit and scope of the invention.

The invention claimed is:

1. An apparatus for creation and delivery of enriched medical suspension, comprising:

a compressed medical fluid unit containing pressurized sclerosant;

a syringe containing medical solution of sclerosant

a suspension delivery catheter including a dual lumen catheter connecting a Venturi-agitating tip assembly to the pressurized medical sclerosant from the compressed medical fluid unit and the medical solution of sclerosant from the syringe,

wherein forcing the pressurized sclerosant through the Venturi-agitating tip assembly causes the medical solution of sclerosant to be drawn into the Venturi-agitating tip assembly such that the pressurized sclerosant from the compressed medical fluid unit and the medical solution of sclerosant from the syringe to mix and form the enriched medical suspension.

2. The method according to claim 1, wherein the compressed medical fluid unit is a syringe containing the pressurized sclerosant.

3. The apparatus according to claim 2, wherein the syringe containing pressurized sclerosant includes a one-way valve.

4. The apparatus according to claim 1, wherein the syringe containing the chemical solution of sclerosant includes a one-way valve.

5. The apparatus according to claim 1, wherein the suspension delivery catheter includes a first end having the

19

Venturi-agitating tip assembly and a second end to which the compressed medical fluid unit and medical solution of sclerosant are fluidly connected for the passage of pressurized sclerosant and medical solution of sclerosant.

6. The apparatus according to claim 1, wherein pressurized sclerosant traveling within the Venturi-agitating tip assembly creates negative pressure inside the Venturi-agitating tip assembly such that the medical solution of sclerosant mixes with pressurized sclerosant and forms the enriched medical suspension.

7. The apparatus according to claim 6, wherein the Venturi-agitating tip assembly includes a spray tip from which the enriched medical suspension is sprayed.

8. A method for creation and delivery of enriched medical suspension, comprising: supplying a compressed medical fluid unit containing pressurized sclerosant; supplying a syringe containing a medical solution of sclerosant; forcing the pressurized sclerosant through a Venturi-agitating tip assembly in a manner drawing the medical solution of sclerosant into the Venturi agitating tip assembly and causing the pressurized sclerosant from the compressed medical

20

fluid unit and the medical solution of sclerosant to mix and form the enriched medical suspension.

9. The method according to claim 8, wherein the compressed medical fluid unit is a syringe containing the pressurized sclerosant.

10. The method according to claim 9, wherein the syringe containing pressurized sclerosant includes a one-way valve.

11. The method according to claim 8, wherein the syringe includes a one-way valve.

12. The method according to claim 8, wherein the compressed medical fluid unit and the medical solution of sclerosant are fluidly connected to the Venturi-agitating tip assembly.

13. The method according to claim 12, wherein the Venturi-agitating tip assembly includes a spray tip from which the enriched medical suspension is sprayed.

14. The method according to claim 8, wherein the Venturi-agitating tip assembly includes a spray tip from which the enriched medical suspension is sprayed.

* * * * *